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## Consultation Outcome Report

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## Pharmacist Prescriber Scope of Practice

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December 2010

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## Executive Summary

The Pharmacy Council of New Zealand (Council), the regulatory body for pharmacists consulted widely on a new scope of practice for pharmacists – the Pharmacist Prescriber scope of practice, in June this year. Seventy-one (71) submissions were received from across the range of stakeholder groups. This report presents the findings and outcomes of the consultation, including the Council responses to the feedback received.

Overall, there was strong support for the proposed scope with 83% of the submissions supporting the proposal, either as presented (39%) or with modifications (44%). Predominantly modifications related to further clarification of the definition of a “collaborative health team environment”; the communication and recording of clinical decisions; the registration requirements and aspects of the education and training for these pharmacists.

17% of the submissions did not support the proposed scope, most of these were from individual medical practitioners or medical organisations. The main reasons included a perceived conflict of interest relating to the financial relationship between prescribing and dispensing and concerns relating to the level of education and training of pharmacists in diagnosis, physical examination and clinical assessment of patients. A number of these unsupportive submissions appeared to be based on an assumption that all pharmacists would become prescribers.

The Pharmacist Prescriber scope of practice is intended to allow only suitably qualified and experienced clinical pharmacists working in a collaborative health team environment to prescribe prescription medicines and controlled drugs to patients under their care. Pharmacists registered in this scope will be known as *Pharmacist Prescribers*. Current workforce data shows that pharmacists working in these environments make up 16% (474 pharmacists) of the workforce.

Enabling pharmacist prescribing requires a legislative change, a process currently managed by Health Workforce New Zealand, Ministry of Health. To this end, the Council submitted its application to Health Workforce New Zealand for pharmacists registered in this scope to hold designated prescriber status (independent prescribing authority) as described in the Medicines Act 1981 in October this year.<sup>1</sup> The Council understands that a decision is to be made in due course by the Board of Health Workforce New Zealand..

The Council believes there are considerable benefits to the public, the government and health professionals in enabling these pharmacists to become designated prescribers as defined in the Medicines Act. As part of its statutory role to protect the public, the Council has carefully considered the risks associated with the addition of prescribing authority to the scope of a clinical pharmacist and Council’s response to feedback received shows how these have been mitigated.

We have consulted widely on this proposal with stakeholders, including other health professionals and the public, and have acted on their feedback to ensure that there is adequate training and supervision of these potential pharmacist prescribers. In particular, to alleviate concerns raised in the consultation, we can now assure stakeholders that pharmacist prescribers will not dispense their own prescriptions nor will they have a vested interest in a pharmacy business.

Thank you for taking the time to respond to this consultation.

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<sup>1</sup> The term ‘independent’ does not mean prescribing in isolation, it is the legal description of the prescribing authority available in New Zealand

### 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 and is responsible and accountable for communicating medicine changes and decisions to the patient's doctor and healthcare team
- will most likely be based in a hospital (wards and clinics), a rest home, a medical practice (under District Health Board and Primary Health Organisation contracts), a hospice or in a secondary/primary interface liaison role
- 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.

## Consultation Purpose

On 2<sup>nd</sup> June 2010 the Pharmacy Council of New Zealand (Council) released a consultation document on the *Proposed Pharmacist Prescriber Scope of Practice*. This document was released in response to section 14 of the Health Practitioners Competence Assurance (HPCA) Act 2003 which requires a regulatory authority to consult on scopes of practice before it is specified by notice published in the *Gazette*. The background section of the consultation document provided the context for the practice of pharmacist prescribers in New Zealand and the determinations made by the Council regarding registration in this scope of practice.

It is proposed that a pharmacist registered in this scope will be a designated prescriber as described in section 2 of the Medicines Act 1981. In order to implement the Pharmacist Prescriber scope of practice the Council has submitted an application to Health Workforce New Zealand, Ministry of Health for pharmacists registered in this scope to hold designated prescriber status. It is also a requirement of this application that the regulatory authority submitting an application to have consulted and addressed concerns raised by stakeholders prior to the submission.

The purpose of the consultation was to:

- outline the context for the proposed scope by detailing the background of pharmacy practice in New Zealand, which included the education and training of pharmacists, their expertise in medicines management and their contribution in optimising medicines related health outcomes for patients
- discuss the likely patient benefits of the scope in New Zealand and those seen in similar jurisdictions
- consult on the HPCA Act 2003 requirements for the proposed scope of practice of pharmacist prescribers. This included:
  - scope of practice definition for a Pharmacist Prescriber
  - the prescribing competency framework
  - the prescribed qualifications (additional education and training requirements)
  - the accreditation standards for the qualification
  - the registration requirements
  - the ongoing competence and monitoring requirements

The consultation document asked a series of specific questions, primarily focused on the HPCA Act 2003 requirements for regulating a new scope of practice. It was not the intention of this consultation process to consider the risks and concerns that are not directly the responsibility of Council as a regulatory authority. These include change processes, costs and workforce issues. However as these issues are intricately linked to the successful implementation of this scope Council stated that it envisaged working in partnership with the organisations that were directly responsible for managing these risks and concerns.

## Consultation Process

The consultation document was released on the Council website on 2 June 2010. The closing date for submissions was 7 July 2010. Council sent out e-mail notification to individual practising pharmacists and to 92 groups to advise of the consultation. These groups included pharmacy organisations, academic and teaching institutions, other relevant health professional groups (including current prescribers), regulatory authorities, potential consumer groups, pharmaceutical industry, other relevant interested parties like District Health Boards, PHARMAC, and the Health and Disability Commissioner. A complete list of the stakeholder groups advised can be found in appendix 1.

## Consultation Respondents

The Council received 71 submissions and a complete list of submitters (and corresponding respondent numbers) can be found in appendix 2. It is difficult to ascertain a meaningful response rate as several responses came from individuals within a group (e.g. pharmacists and medical practitioners). However based solely on the number of groups advised by Council (which was 92), a response rate of 77% could be determined although this rate should be viewed within the identified limitation. It is not known how many more individuals or groups received the consultation document through other avenues and networks. The range of stakeholder groups and number of submissions received is presented in the table below (Table 1).

A submission form was available online and a response to each question was required before a submitter could respond to the next question resulting in all questions being answered by an online submitter. 53 submissions (75%) were received online and 18 submissions (25%) were received in writing, in a letter style format.

**Table 1**      **Response to the Consultation**

Stakeholder Group	Number of Submissions
Academic/Teaching Organisation	2
Accident Compensation Corporation (ACC)	1
DHBNZ <sup>2</sup>	1
District Health Board (DHB)	3
Funding Authority	1
Health and Disability Commissioner (HDC)	1
Medical - General Practice	4
Medical - Specialist	5
Medical Centre	1
Medical Organisation	7
Nursing Organisation	3
Other Health Professional Group	3
Pharmaceutical Industry	1
Pharmacy - community	13
Pharmacy - hospital	10
Pharmacy - other	5
Pharmacy Organisation	5
Primary Health Organisation (PHO)	2
Regulatory Authority (Health Professions)	3
<b>Total</b>	<b>71</b>

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 in appendix 3.

<sup>2</sup> DHBNZ refers to the collective submission of 20 DHBs

## Submissions Analysis

The submissions analysis looked at the feedback received in four ways to ensure that Council was able to respond in a meaningful way. In addition this approach was taken to ensure that the analysis was reflective of submissions received online (i.e. as answers to a series of questions) and to those received in writing (highlighting specific areas of concerns or suggestions). The analysis grouped the issues for each of the questions asked in the consultation and Council has considered these issues and responded accordingly.

### Analysis 1 Overall Support for the Proposal

Analysis 1 included all 71 submissions (100%) and identified submissions which indicated an acceptance of the Pharmacist Prescriber scope of practice. Essentially in this scope of practice the pharmacist is a designated prescriber working in a collaborative health team environment to optimise medicines related health outcomes for patients under the care of the collaborative health care team.

The submissions were analysed for levels of support and three main groups were identified:

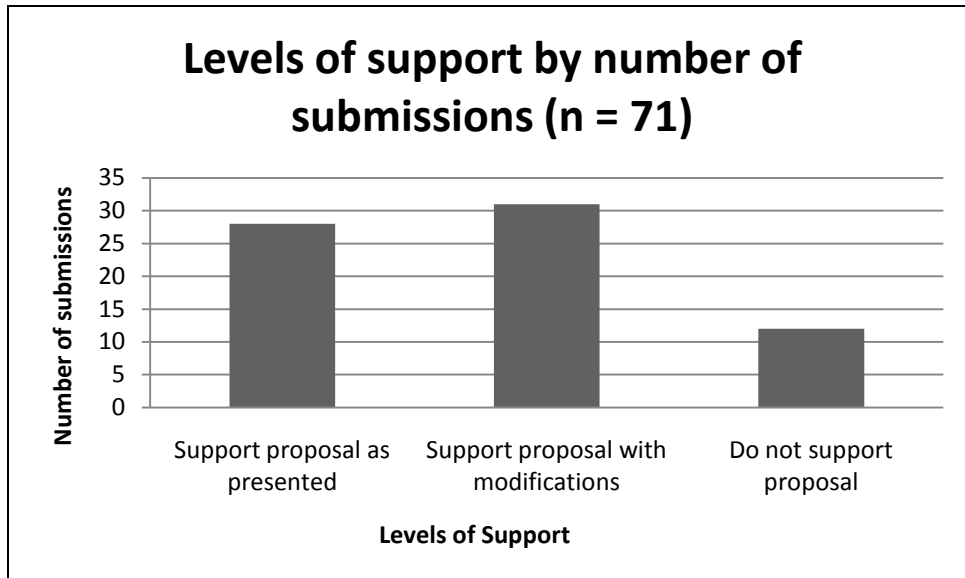
1. submissions that supported the proposal as it was presented with no major changes or concerns i.e. *support the proposal*;
2. submissions that supported the proposal in principle but had further questions, concerns or suggested modifications i.e. *support the proposal with modifications*.
3. submissions that did not support the proposal of the Pharmacist Prescriber scope of practice i.e. *do not support the proposal*

The results of this analysis are presented in Table 2 and Graphs 1 and 2.

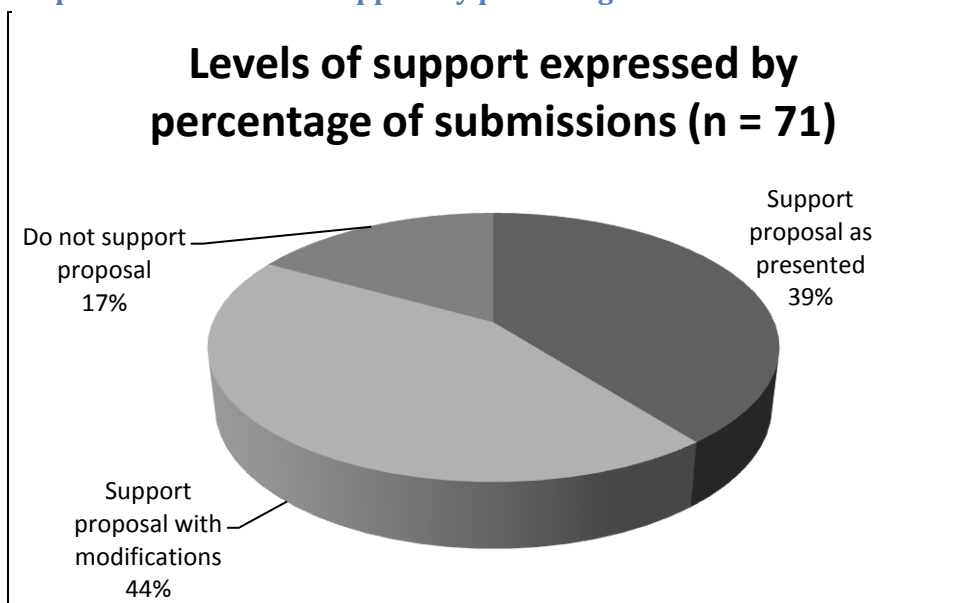
**Table 2**      **Levels of Support**

Level of Support	Number of Submissions	Percentage
Support proposal as presented	28	39%
Support proposal with modifications	31	44%
Do not support proposal	12	17%
<b>Total</b>	<b>71</b>	<b>100%</b>

**Graph 1** Levels of Support by number of submissions



**Graph 2** Levels of Support by percentage of submissions



### Overall Supportive Feedback (respondent number)

The following overall feedback regarding the proposal was received from across the stakeholder groups. Respondent numbers are used as identifiers (see appendix 2).

*We would like to congratulate the Pharmacy Council of New Zealand for all their efforts to date to enable pharmacist prescribing in New Zealand. Although a dearth of literature exists on pharmacist prescribing, in the United Kingdom, the issue of safety has not been a concern (51)*

*Looks like a great development. Well done in pulling this together (48)*

*Overall this is an important role and a significant proposal and opportunity. It needs to be well sold and implemented and any misunderstandings or issues resolved. Important that the advantages to all are*

*emphasised and that the similarity of functions that GP's and Pharmacist prescribers will overlap will be reflected upon in context of where they work and the collaboration of the healthcare team (6)*

*Thank you for the opportunity to comment on the proposed Prescribing Scope and competencies. This is an exciting development for Pharmacy and we look forward to its progression. We canvassed our membership and have collated the responses. Overall there was a positive response, as you will note from the comments (55).*

*The Pharmaceutical Society strongly supports the introduction of a pharmacist prescriber scope of practice, and has every confidence that pharmacists who choose to embrace it will undertake this new role competently and safely (60)*

*I support the proposed Pharmacist Prescriber Scope of Practice. The Pharmacist Prescriber role will benefit aged care providers; integrated healthcare providers and GPs by providing a prescriber with a medicine management focus as part of the patient healthcare team (3)*

*I think that it is a well designed proposal. I agree with the necessity of further education and definition of scope of practice (14)*

*The consultation document is thorough and comprehensive and addresses many issues also faced by nurse practitioners. The College looks forward to working with pharmacist prescribers in this new collaborative role (50).*

*Overall a very extensive and complete paper, logical, well-sequenced, with full background which enabled the reader to clearly follow the purpose, development and context. Due attention has been given to risks as well as benefits, and it is acknowledged any change must be in the interests of public health and safety. The scope is also supported by the background document's thorough descriptions of current pharmacist roles and overseas comparisons. However, it should be noted that physiotherapists do not have a prescribing scope of practice, and so have a limited point of reference (16)*

*A very thorough and thoughtful proposal. It clearly identifies the benefits to patients of extending the role of pharmacists and establishes the framework for ensuring competence amongst those holding the proposed scope. Pharmacists are clearly a major resource within the primary care team and the Osteopathic Council recognises the benefit to osteopathic patients of the creation of the Pharmacist Prescriber role. It is imperative that the health system maximises the use of the skills within the workforce (34)*

*The Clinical Services Directorate, of the Accident Compensation Corporation has reviewed the consultation documents for the Proposed Pharmacist Prescriber Scope of Practice and has no specific comment or concern. The proposed accreditation programme and competence standards seem to meet the requirements to ensure safe prescribing by pharmacists who meet the training requirements and gain certification from the Pharmacy Council as Pharmacist Prescribers (52)*

*The College and the Society support the proposal in general terms as we agree that pharmacist prescribers may be able to improve services to patients by prescribing within clearly set parameters. These parameters must reflect the fact that in general terms pharmacists are not diagnosticians. They could support the activities of general practitioners and physicians, who may be in short supply, thus enabling these doctors to focus on their core competencies (64)*

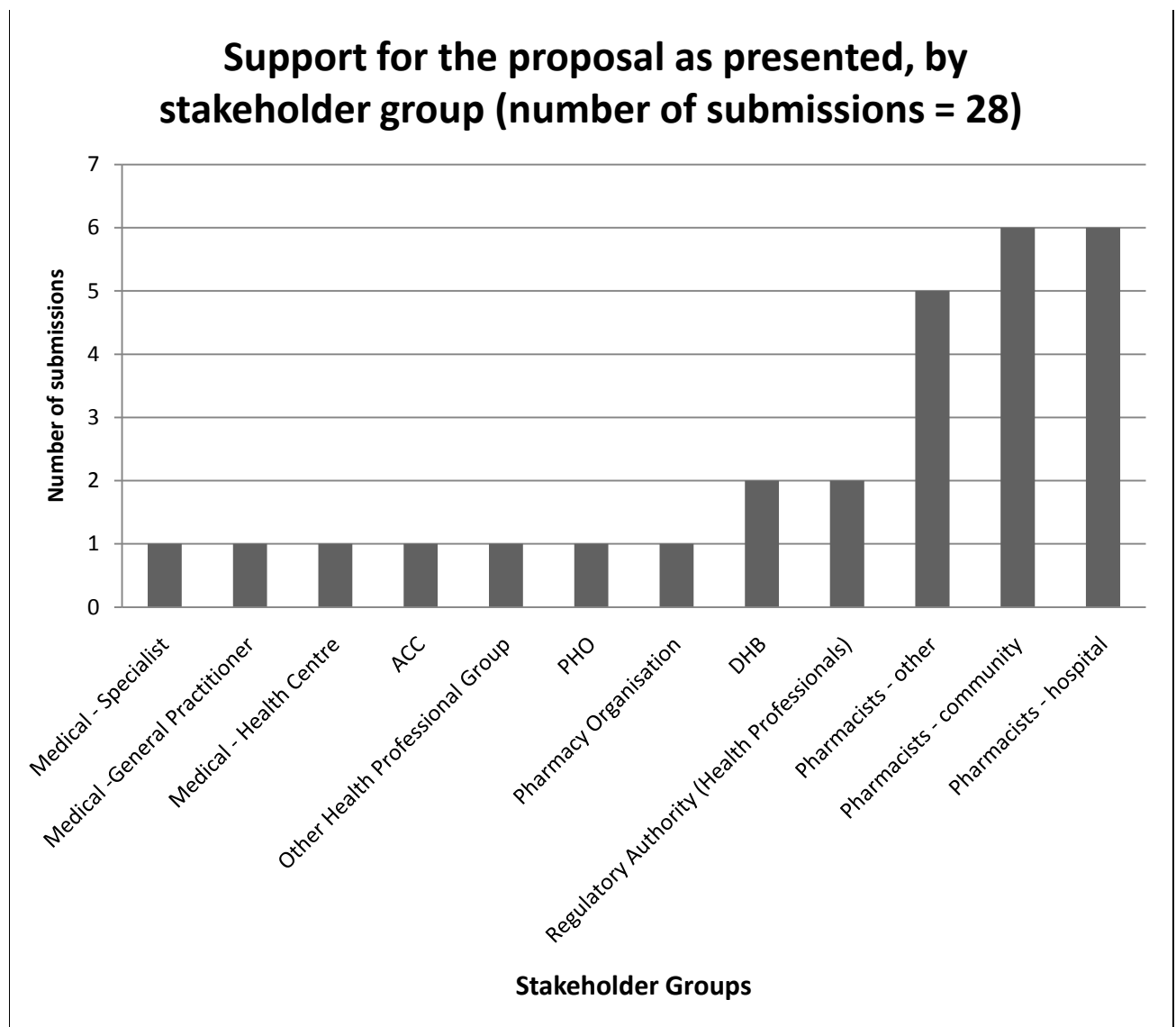
*We would like to congratulate the Pharmacy Council of New Zealand for producing such a comprehensive document where the roles, responsibilities, prescribing requirements are clearly described. Pharmacists are well respected in the area of medication management and their expertise has been an indispensable source for*

nurses and doctors. We believe that pharmacists are professionals who are best positioned in medication management. We hope that a further model can be develop where clinical nurse specialists and nurse practitioner prescribers can work in a collaborative manner with pharmacist prescribers to deliver better care for patients. There are currently a limited number of nurse practitioner prescribers and clinical nurse specialists especially in non hospital settings (e.g. Rest Homes and Institutional setting) where there is limited medical practitioner availability. These settings can benefit from the collaborative health care model. (34)

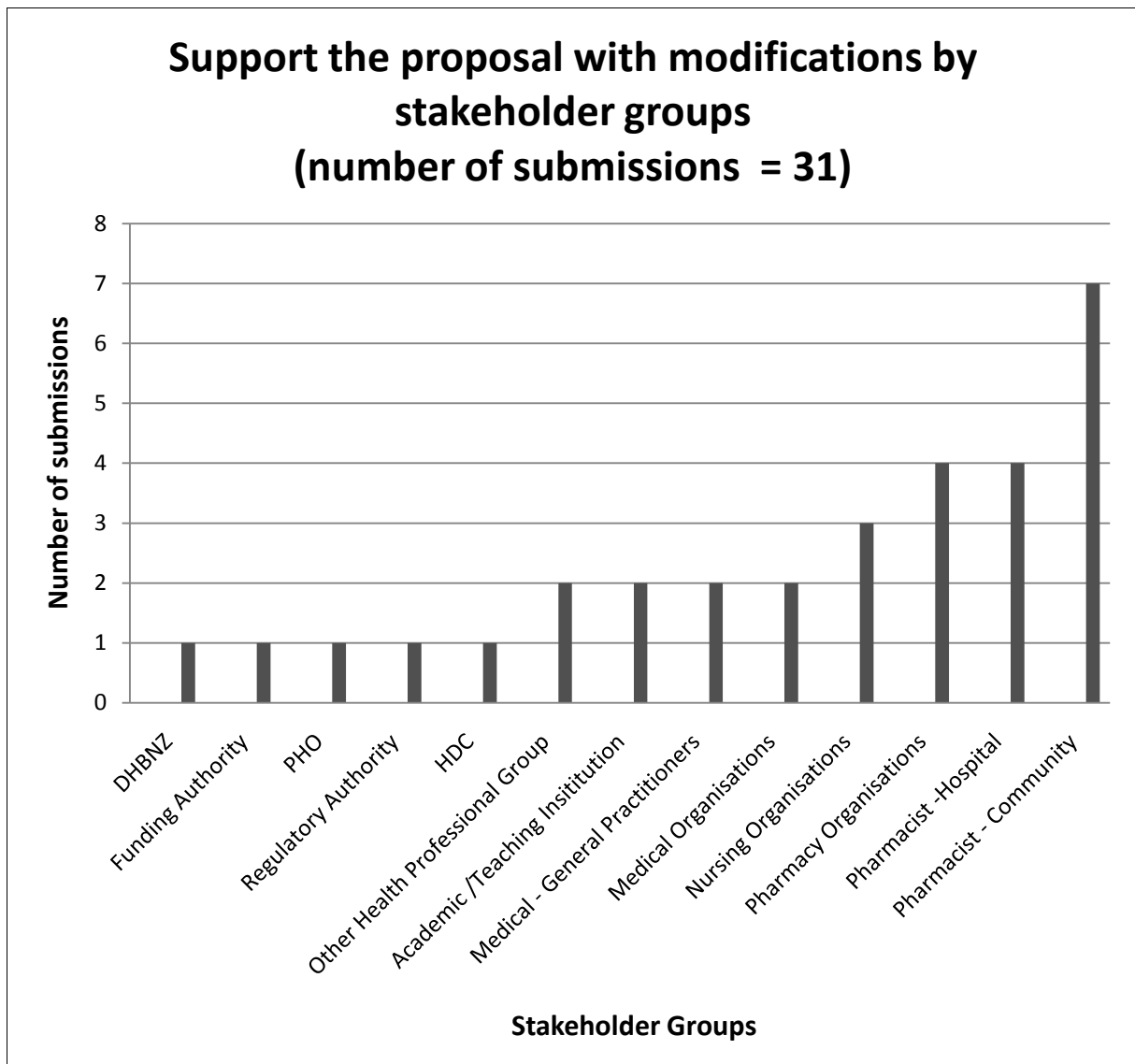
## Analysis 1a Support for Proposal by Stakeholder Groups

Analysis 1a is a subset of Analysis 1 and includes all 71 submissions (100%). This analysis looked at the stakeholders groups within each level of support. The results are presented in Graphs 3, 4 and 5.

**Graph 3 Stakeholder groups supporting the proposal (as it was presented with no major concerns or changes)**

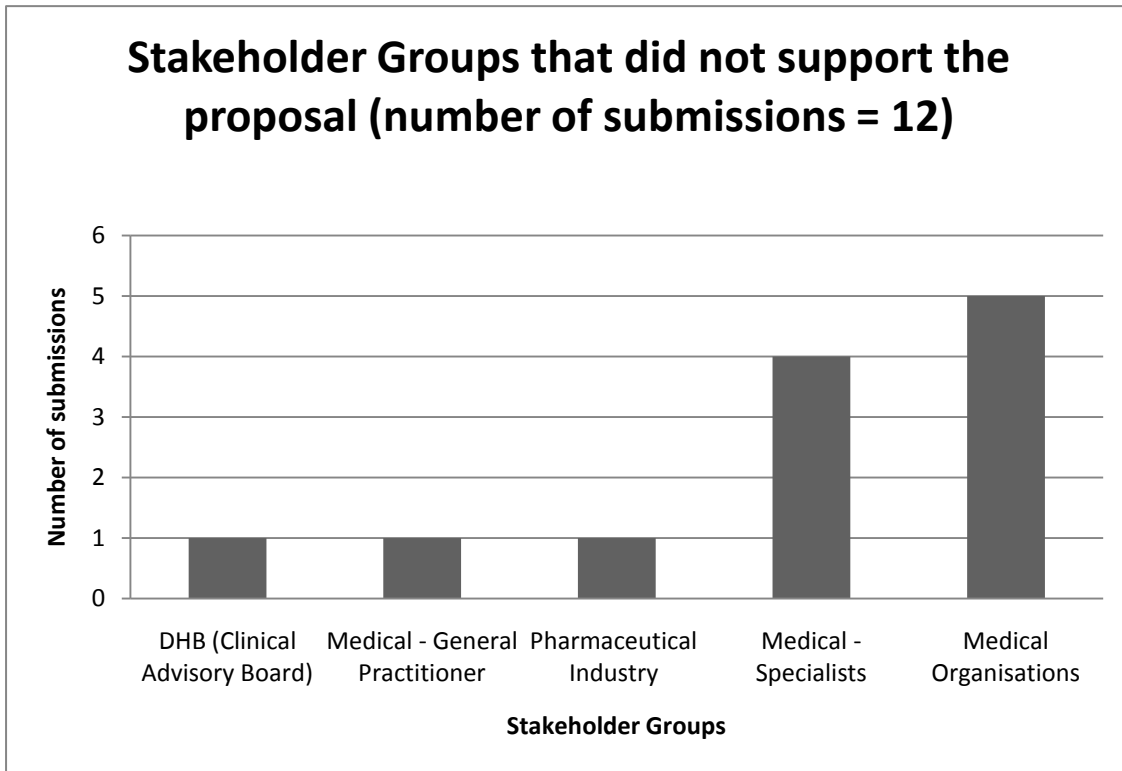


Graph 4 Stakeholder groups supporting the proposal with modifications<sup>3</sup>



<sup>3</sup> DHBNZ refers to the collective submission of 20 DHBs

**Graph 5 Stakeholder groups that did not support the proposal**



## Analysis 2 Feedback by Stakeholder Groups/Individuals

Analysis 1 and 1a indicated that feedback was reflective and unique to the area of professional practice of the stakeholder group responding. **Analysis 2** therefore is qualitative and is a collation of general feedback by area of professional practice of the stakeholder groups. The responses are directly quoted from the submissions in order to convey accurately the concerns and context of the submitter. It represents the general feedback to the proposal received from 18 written submissions and 39 online submissions and therefore collectively represents feedback from 80% of the submissions. Written submissions which included responses to the specific questions asked in the consultation were included in analysis 3.

### Pharmacy Profession

Overall individual members and organisations of the pharmacy profession supported the Pharmacist Prescriber scope of practice.

Feedback from the respondents in this stakeholder group is included below. Respondents can be identified by their respondent number (refer to Appendix 2)

### Feedback (respondent number)

I support the proposed Pharmacist Prescriber Scope of Practice. The Pharmacist Prescriber role will benefit aged care providers; integrated healthcare providers and GPs by providing a prescriber with a medicine management focus as part of the patient healthcare team.	3
Overall this is an important role and a significant proposal and opportunity. It needs to be well sold and implemented and any misunderstandings or issues resolved. Important that the advantages to all are emphasised and that the similarity of functions that GP's and Pharmacist prescribers will overlap will be reflected upon in context of where they work and the collaboration of the healthcare team	6
In principle I support pharmacist prescribing within a collaborative health team environment for example rest homes.	8
I see pharmacist prescribing being relevant in areas such as palliative care in light of the shortage of GPs and specialists available to work in this area (particularly the rural areas of New Zealand).	10
I think that it is a well designed proposal. I agree with the necessity of further education and definition of scope of practice.	14
Wairoa will be in crisis for GPs within the next 5 to 10 years, as currently over half the GPs are locums (often from overseas) and the others are either looking at retirement or reduced hours within that time frame. An illness or death of one of these GPs would put considerable pressure on the ability to provide adequate healthcare services in Wairoa. An integrated healthcare system is being proposed. I have been approached by one of the GPs to see if I would be interested in being involved with this as a pharmacist prescriber. Wairoa is a high need area. This Pharmacy already has a high level of involvement with Community Mental Health providers, including attending the Psychiatrist clinics. We have a high level of involvement with the GP practices giving feedback on interactions, GP queries on medicine information, help in identifying the drug involved with a drug side effect, collaborative involvement with drug dependence reduction. Also with GPs themselves with involvement in their CE monthly meetings, presenting on new drugs, updating regulation changes doing medication therapy assessments. We are in the process of trying to develop a clinic, GP referred, for diabetes education and assessment of therapy with the pharmacist and nurses working together in collaboration with the GPs.	19
I currently work part time in a community pharmacy and part time as a community based clinical pharmacist following patients after discharge from hospital and following referral from GPs for those patients they would like a more in depth medicine review undertaken on. I find during these consultations the need to re-align medicines and sort out what is current. The benefit for me would be the ability to generate prescriptions within agreed criteria with the GP or hospital team to allow the patient to get the benefit intended from their prescribed medication and also to allow more accurate feedback to other team members of the patients true medication regimen. I can make a request to a GP for a prescription currently and am fortunate to have developed close relationships with a number	37

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of GP practices, and so have a foot in the door already. I feel the development of a Pharmacist Prescriber would benefit the health team and allow a smoother transition following discharge for those patients at higher risk of adverse events or medication mismanagement. The data both Nationally and Internationally shows that medicines are a major determinant for unwanted hospital admissions. In addition we have initiated some clinics in 2 local resthomes and are developing good practices with the staff and GPs who services these resthomes

Great work, as a specialist palliative care pharmacist very interested in this development. 38

I am a partner in a busy rural/provincial community pharmacy. The town has a shortage of GPs and use of standing orders for practice nurses is being rolled out (who are allowed to practise this way while studying papers in assessment). This would result in patients having nurse consultations where a medicine may be given e.g. antibiotics for a urinary tract infection. There are moves to extend this to community pharmacists in future (a level 4 service in effect). Creating prescriptions for new and continuing medications is something that, at practice level, is done increasingly by nurses. I see a role for community pharmacists in this process, one which would improve patient safety and therapeutic outcomes. The pharmacist prescriber scope of practice needs to enable such developments. Perhaps there is room to allow for closely supervised, active practice (akin to an intern scope / recognition of experience), while undertaking training towards the pharmacist prescriber scope. It may be possible to pilot a project of this nature here on the West Coast. 44

For me in my current area of practice (rural community pharmacy) where patients are often waiting 2-3 weeks to see a GP the drivers for pharmacist prescribing are improving accessibility and delivering a quality, timely service to patients. It is good to see some exclusion (exceptions rather than rule) which may otherwise see many patients miss out on the chance to be offered a service such as this where the potential benefits likely significantly outweigh perceived conflicts. 45

It takes a minimum of 5 years to train as a pharmacist. To qualify to become a designated prescriber a pharmacist must then have at least three years of recent, clinically oriented, patient -focused post-registration experience in hospital or community based settings and have completed an accredited postgraduate course in clinical pharmacy which will include a prescribing practicum and which will be carried out under the supervision of a doctor. In the shorter term there are likely to be more hospital based pharmacists that meet these criteria. 55

It is important to stress (more?) that only a relatively small group of pharmacists are likely to be in a position to prepare for such a role if the change is adopted – in the first few years at least. In addition, the pharmacists who choose to qualify for and take up this role will be obligated to prescribe within their own professional area of expertise, just as doctors and nurse prescribers do now. 55

There are a number of clinical pharmacists in the hospital and community setting who are currently working at this advanced level, and NZHPA supports the Pharmacy Council's application to the Ministry of Health to have such pharmacists recognised for (and responsible for) their valuable contribution to an individual's health as part of their healthcare team(s). 71

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### Medical Profession

Submissions from the medical profession were received from individual medical practitioners (General Practitioners (GPs) and specialists), medical organisations and a medical centre. Comments received from this group indicated both support and concerns on the proposed Pharmacist Prescriber scope of practice.

A common perception held by many of these respondents was that the proposed scope would be 'open' to all pharmacists. This resulted in obvious patient safety concerns where the pharmacist may not be part of a collaborative health team environment and may be working independently in a community pharmacy practice.

The main reasons for not supporting the proposal included a perceived financial conflict of interest (prescribing and dispensing); concerns regarding the lack of education and training pharmacists receive in diagnosis, physical examination and clinical assessment; and a lack

of recognition and understanding of a pharmacist's knowledge and skills proposed for this scope of practice.

Feedback from the respondents in this stakeholder group is included. Respondents can be identified by their respondent number (refer to Appendix 2)

### **Supportive Feedback (respondent number)**

As a GP who has an excellent relationship with my local pharmacist, I can see how this could work well for us, although there are also a number of potential pitfalls. Positive aspects are: **1**

- Extra level of safety regarding paediatric drug doses in particular.
- Patients with tricky medication issues will be identified, and discussed with the GP.
- Convenience for patients – patients for whom it is probably not necessary for them to see a GP can have access to appropriate treatment
- GPs possibly may be freed up to see other patients than those 'minor ailment' category, although this may result in a loss of income for the GP.
- From a GPs point of view we often have a great deal of difficulty trying to decipher discharge medications which were done in a hurry by a house officer at the hospital who does not know the patient. Having a community pharmacist work closely with discharging house officers would really help with this, and would also ensure that patients do not remain on medications which they were supposed to have stopped once leaving hospital, which frequently happens. Another frequent problem is patients thinking that they can stop their medicines once the supply from the hospital runs out. I think an extra level of input here at the primary/secondary interface would aid patient compliance and understanding.

Pharmacists have huge knowledge that is not used enough **21**

Overseas research clearly documents how pharmacist prescribers may improve patient access to health services and contribute to the management of chronic disease, especially within areas of greatest need. In New Zealand we are faced with similar health challenges in regard to health workforce shortages and increasing demands made upon health services. From this service delivery perspective, the development of a scope of practice for prescribing pharmacist has merit. This proposal goes some way to address the issues highlighted in the Horn report, in that in New Zealand health care needs to be provided closer to the patient and more conveniently. We need innovation in the workforce and we need to look at service configuration. The College and the Society support the proposal in general terms as we agree that pharmacist prescribers may be able to improve services to patients by prescribing within clearly set parameters. These parameters must reflect the fact that in general terms pharmacists are not diagnosticians. They could support the activities of general practitioners and physicians, who may be in short supply, thus enabling these doctors to focus on their core competencies. **64**

General practitioners and patients greatly value the important contribution pharmacists make to patients care. The College strongly supports collaboration between health professionals. In the interests of effective and efficient healthcare and health promotion it is vital that health workers work together with the common goal of improving the health of individuals and populations. General practitioners are the lynchpin in the health system and are well aware of the difficulties interest in coordinating patient care across primary and secondary care, mental health services, maternity services, disability support services and so on. Collaboration is essential to avoid the inefficiencies, safety risks and poor quality care that result from fragmented care. General practitioners interact frequently with Community Pharmacists but seldom with hospital based pharmacists. Not surprisingly the majority of the feedback which we received from members reflected the assumption that Community Pharmacists would become prescribers. Reading the consultation document did not give GPs reason to question this assumption. An explicit and unambiguous statement easily interpreted by non pharmacist early in the document or in a covering letter would have enabled our members to identify what the College is informed is the actual gist of the Pharmacy Council proposal, and hence understand that the majority of pharmacist prescribers will be working in secondary care environments, and that a community pharmacist wishing to become a prescriber would not be able to own a pharmacy. **66**

Pharmacists are an essential and undervalued part of the primary care team. Our practice works in close **70**

association with our pharmacist to the patient's benefit.

### **Concerns and Risks (respondent number)**

Concerned that patients may begin to use the pharmacist prescriber instead of their GP. There is the potential for abuse of the rights here on both sides. In attending the pharmacy for their repeat medicines, not only do patients miss out on the relationship with their GP, they do not get a private consultation, and there is a missed opportunity not only for physical examination, but also for opportunistic screening such as skin checks, prostate and breast checks, cervical screening, depression screening etc. Perhaps allowing pharmacist prescribing is de-valuing the GP consultation. 1

Prescribing rights should not be extended to those who would make their prescribing decisions solely on the subjective account of the recipient, without the necessary training for , or the practice setting to allow, the verification of this objectively by informed clinical observations, and/or further investigations where required. Despite the fine words in which it is couched, the proposal trivialises prescribing by potentially removing it from its proper clinical setting. 22

In order the prescribe you need to be competent in the following areas: 23

- Take a history and examine the patient . Will they really be able to diagnose and know when they are out of their depth?
- Have access to the appropriate investigations (pathology and radiology) and understand their implications. Will for example when talking to the tired lethargic patient be able to rule out hypothyroidism, iron deficiency anaemia, coeliac disease or cancer?
- Have access to the full clinical record of the patient including drug alerts for side effects and allergies. Who will have the responsibility for giving pharmacists access to this information and what are the privacy implications?

There is a large conflict of interest for community based pharmacy which does not appear to be fully addressed in the proposal. The consultation document has already commented on the financial issues. I do not believe this conflict of interest can be resolve through audit 23

I believe, any change initiated by a pharmacist should be communicated back to the primary medical practitioner with responsibility for that patient. Will this occur? If I attended a pharmacist prescriber in Wellington would the information get back to my GP in Christchurch? Would the pharmacist have to ring the GP to get the appropriate medical background of the patient? Who will communicate back to the pharmacy prescriber regarding any adverse outcome of their advice or change in medication? Is this another job for our overworked medical workforce? This is critical for any healthcare provider. 23

I find the model for this consultation constrictive. The key question is what is a collaborative health environment and in my view that is not the model that exists in New Zealand at this point except perhaps in secondary care facilities. It needs a more explicit definition to avoid the problems that could potentially occur. There is a significant conflict of interest arising out of the dual roles of prescribing and dispensing if this proposal is applied to community pharmacy in its current form that will not be adequately addressed by audit. If community pharmacy continues to exist in its current form this will lead to fragmentation of care which could decrease safety and it will likely lead to increased pharmaceutical costs. General Practitioners will have their workloads increased. The proposal is silent about the extremely common practice of pharmacists selling add-on unproven therapies for the purpose of profit which is an ethical blight on the profession. Unless there is a very significant restructuring/evolution of the current model this will cause more harm than good. 30

AMPA does not see any patient benefits in the 'pharmacist prescriber' proposal, but does see big risks in pharmacists or any other person not trained in diagnosis prescribing drugs beyond those on the OTC list. 35

Pharmacists are knowledgeable, ethical and valued members of the health care team. They are not however comprehensively trained in differential diagnosis, a prerequisite to prescribing. As we have said previously, at the heart of any decision to prescribe is the need to assess and diagnose the undifferentiated patient across different clinical and cultural settings. Only then can a treatment regimen (which may include prescribing), be developed. NZMA submitted on a substantially similar proposal back in 2007. We were not supportive at that time and there is nothing in the revised proposal to make us change our mind. In summary our position remains that for a registered health practitioner to be able to prescribe their training should be comparable to that of a registered medical practitioner. 56

In summary, that RANZCP believes that greatest value added by pharmacist prescribing would be the role of a collaborative (or Level 4) prescriber in the first instance. Independent prescribing runs the risks outlined, including inadequate or delayed diagnosis of more complex medical problems. There is the further problem of patients who will avoid primary health care services that they need to pay for – a common scenario. An additional issue for consideration is the medico-legal responsibility associated with prescribing. It needs to be considered whether the pharmacist is ready to take the medico-legal responsibility if there are adverse reactions, and if so, how they will be supported. The RANZCP does not support pharmacist prescribers being able to initiate different treatments to those prescribed by the patient's treating doctor or to discontinue treatments by the patient's prescribing doctor in the absence of communication with that doctor. We wish to highlight that there is significant value in pharmacist colleagues checking prescriptions and challenging the prescriber on the basis of possible prescribing errors or adversities to the patient, and hold pharmacists and their skills and knowledge in high regard

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From the data presented, in the consultation document, the majority of pharmacists in New Zealand work in a community setting. It can be assumed that the majority of community pharmacists are not diagnosticians and are working in an individual and not truly collaborative setting (with other multidisciplinary colleagues including medical practitioner). Consequently the College would not support extending their scope of practice into the realm of prescribing.

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The issues we have identified are:

(a) Access to patient records regarding co-morbidity, drug allergies and psycho-social data. How might the prescribing pharmacist have access to this data?

(b) Continuity of care. How does the pharmacist working in the community interact with the physician or the hospital regarding discharge information, management plans and the transfer of clinical information amongst the health care providers? One of the critical factors would be to ensure any change to the patient's medication is accurately recorded, is updated on a regular basis and communicated to all other relevant health care providers.

(c) Working in isolation. For health professionals to function effectively they must work closely with their peers. From whom would the community pharmacist seek a second opinion regarding their clinical decision making?

(d) The issue of patient safety. All of the above points relate to this issue.

(e) We note that the issue of the pharmacist prescriber owning the pharmacy would be addressed. However, this may be difficult to achieve particularly in isolated areas where there is only one pharmacist or in places where the general practitioner is not always available outside normal hours i.e. on the weekends.

We are sceptical that the provision of pharmacist prescribers will have any positive impact on patients managed on Intensive Care Units (ICU). Further, we are uncertain that a need for pharmacist prescribers has been demonstrated in any area of health care provision and is concerned that the costs (both overt and occult) of implementing this change will be significant and ultimately not justified by any improved health care outcomes.

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In NZSA's view any extension to prescribing practice for other health practitioners imposes additional costs on the health system. The increased access to medicines by consumers may be a benefit if it reduces hospital admissions and visits to GPs or specialists. But these gains have to be measured against the potential rise in medication errors and treatment costs associated with that, the increase in medicines dispensed which occurs from wider access and the added waste of medicines dispensed and unused, and the increased costs of referred testing to validate diagnosis and the burden of unidentified disease. We suggest that the cost benefit of ever widening prescribing rights and the administration of drugs to other registered health practitioners needs to be considered carefully in light of the overall impact on NZ's limited health budget

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## Feedback received from other stakeholder groups

Other Stakeholder Groups (respondent number)	General Comments (extracts from submissions)
Academic/Teaching Institutions (University Based) (33)	<p>We would like to congratulate the Pharmacy Council of New Zealand for producing such a comprehensive document where the roles, responsibilities, prescribing requirements are clearly described. Pharmacists are well respected in the area of medication management and their expertise has been an indispensable source for nurses and doctors. We believe that pharmacists are professionals who are best positioned in medication management. We hope that a further model can be developed where clinical nurse specialists and nurse practitioner prescribers can work in a collaborative manner with pharmacist prescribers to deliver better care for patients. There are currently a limited number of nurse practitioner prescribers and clinical nurse specialists especially in non hospital settings (e.g. Rest Homes and Institutional setting) where there is limited medical practitioner availability. These settings can benefit from the collaborative health care model.</p>
Accident Compensation Corporation (52)	<p>The Clinical Services Directorate, of the Accident Compensation Corporation has reviewed the consultation documents for the Proposed Pharmacist Prescriber Scope of Practice and has no specific comment or concern. The proposed accreditation programme and competence standards seem to meet the requirements to ensure safe prescribing by pharmacists who meet the training requirements and gain certification from the Pharmacy Council as Pharmacist Prescribers. Thank you for the opportunity to review the consultation documents and provide feedback.</p>
Clinical Advisory Board – Auckland District Health Board (62)	<p>1. In 2007 ANZCA (Australia &amp; New Zealand College of Anaesthetists) supported the development of an Advanced Pharmacist Scope of Practice and argued that gaining designated prescriber status should not be part of this scope. They supported collaborative prescriber status as being more appropriate for pharmacists. Central to this decision was the statement by the Pharmacy Council and the Pharmaceutical Society that pharmacists are not diagnosticians.</p> <p>2. The Auckland DHB Clinical Advisory Board continues to support the view of <i>an advanced scope of practice for suitably qualified and experienced Pharmacists, and Pharmacists as collaborative prescribers within a collaborative healthcare team environment.</i></p> <p>We do not see that the current proposal provided changes this position, neither do we consider that the additional information provided clearly answers the questions regarding the provision of essential skills, competencies and behaviours re: assessment and diagnosis. Additionally, we remain concerned that “Pharmacists do not believe that they should have a restricted list of medicines or diseases from which they may prescribe (page 44)”.</p> <p>3. We are not clear that the current problem that this proposal is endeavouring to meet is clearly addressed. What is the current problem in New Zealand that underpins the need to broaden the range of healthcare providers with prescribing rights? If there is a shortage of Doctors or Nurse Practitioners in key areas, and is it prescribing Pharmacists that are required?</p> <p>4. We can envisage Pharmacists working as part of a collaborative healthcare team in a hospital setting prescribing as per the example provided e.g. changing IV antibiotics to oral etc – however we have junior doctors that can do that already. If there were hospitals where there were no junior doctors, then this might be</p>

<p>Clinical Advisory Board – Wairarapa District Health Board (68)</p>	<p>feasible, such as more rural and remote communities. However this particular situation would easily be overcome by seeking a telephonic order from the doctor in charge of the patient.</p> <p>5. We are not clear of the problems described with the primary secondary care interface. One of the key attributes of clinical practice is the requirement for good assessment skills (underpinned by detailed knowledge of anatomy, physiology and pathology). It is not enough to simply repeat a prescription, one needs to assess whether the patient still requires the drug and that not only means a history but often a clinical examination. Nurse Practitioners acquire these skills through advanced training but we do not see where such training is provided to pharmacists as part of their current scope, or this proposed scope of practice in sufficient depth to meet these requirements.</p> <p>The principle of collaborative prescribing is built in the Pharmacist Prescriber registration and practice. This will optimise the pharmacist prescriber's input to the health service while ensuring safe and optimum patient treatment.</p>
<p>DHB (5)</p>	<p>Recognition that this is not a novel practice model, but that the pharmacist prescriber is a formalised practice model in several developed countries including the UK and USA.</p> <p>Would like to emphasise the importance of the collaborative health team environment as an integral part of pharmacist prescribing.</p>
<p>District Health Boards of NZ <sup>4</sup>(67)</p>	<p>The definition for a Collaborative Health Team is not definitive enough. Additionally, it is unclear from the documentation provided how it would be determined that this condition was met when considering an application for pharmacist prescriber status.</p> <p>Thus we believe further work in this area is required. The following are some suggestions for consideration:</p> <ol style="list-style-type: none"> <li>a. A pharmacist applying for prescriber status should be able to provide a "practice plan" that is endorsed by the clinical lead of the Collaborative Health Team". This plan should provide information on the scope of practice, type of patients and areas that it is expected the pharmacist will be prescribing.</li> <li>b. Prescriber status should only apply to work the pharmacist does within the specified team. If they change teams then they should be required to be recertified.</li> <li>c. Access to patient health information should be direct and immediately available to the pharmacist and they should not need to request access. The nature of access to patient health information should be documented in the practice plan. It should include history and physical examination and essential diagnostics are essential for appropriate prescribing</li> <li>d. Ongoing care where the medication is long term, there is an agreed dosage range and observable indicators are being met is appropriate for both GP and Specialist agreed prescriptions</li> <li>e. The pharmacist would ideally work at the same site as the collaborative health team, or, have access to a comprehensive electronic clinical record.</li> <li>f. We note the National Health IT Board has an objective to move to an electronic health record accessible directly by health care providers. Direct access to this information should not, in itself, be an indicator that the pharmacist is in a collaborative health team.</li> </ol>
<p>Health and Disability Commissioner (9) Nursing - Professional</p>	<p>Overall, I support the Pharmacy Council's proposal. I trust the following comments are helpful in developing the new Pharmacist Prescriber scope of practice .</p> <p>The consultation document is thorough and comprehensive and addresses many</p>

<sup>4</sup> DHBNZ refers to the collective submission of 20 DHBs

Organisations (50)

issues also faced by nurse practitioners. The College looks forward to working with pharmacist prescribers in this new collaborative role.

Nursing - Professional Organisations (51)

We would like to congratulate the Pharmacy Council of New Zealand for all their efforts to date to enable pharmacist prescribing in New Zealand. Although a dearth of literature exists on pharmacist prescribing, in the United Kingdom, the issue of safety has not been a concern. There are further issues for Council to consider in their current deliberation including: 1. Confidentiality of patients' records. With the potential for multiple health professionals being able to or is given access to patients' clinical records, confidentiality may be an issue. 2. Although pharmacists are practitioners who are competent in dealing with patients' medication management needs, establishing therapeutic relationships with patients is unique and more challenging. Nurses are trained and educated in this area and as a profession, have skills and knowledge in the development of therapeutic relationships. Can nurses work with pharmacist to mentor pharmacist by providing guidance and practical knowledge to extend pharmacists skills in therapeutic relationships with patients?

Nursing - Professional Organisations (53)

NZNO thanks you for this opportunity to feedback on the draft Proposed Pharmacist Prescriber Scope of Practice.

We **recommend** that you:

- **note** our support in principle for the role;
- **agree** that there is potential for the development of collaborative nurse-led clinics in pharmacies to provide better access to primary health care especially for rural and socio-economically disadvantaged populations;
- **agree** that an authorized pharmacist scope may clarify the education, training and skills needed for assessment and diagnosis, which are not within the current pharmacists scope, and would therefore contribute to safer, more effective health care;
- **note** the potential for misinterpretation of this new scope and develop a clear communications strategy to address this risk;
- **note** that we support the development of new models of care within the regulated health workforce.

Other Health Professional Groups (59)

We previously made a submission to the Pharmacy Council (in 2007) stating our general but cautious support for an extension to pharmacists scope of practice to enable prescribing. We noted several concerns in this submission, particularly in relation to the potential fragmentation of care which could eventuate as a result of such a change to pharmacists practice. We are pleased to note that some of our concerns have been addressed in this subsequent document which sets out collaboration as a pre-requisite for pharmacist prescribing. Although this is reassuring, the current model of health care delivery which is operating within a primary maternity health care environment does not easily allow for the level of collaboration required to enable pharmacists prescribing.

We can envisage the values that pharmacist prescribing would add within a complex tertiary care environment within specialist teams, where a multidisciplinary approach is required. It is however difficult to quantify the value that pharmacist prescribing adds to the primary maternity care environment where current model of care (the Lead Maternity Carer (LMC) model) is one of case management. If a midwife LMC is unable to treat a woman presenting with a problem, it is generally because it is beyond their scope of practice (e.g. hypertension) and necessitates a referral to an obstetric specialist or medical practitioner. In order to enable pharmacists prescribing in a primary maternity care context, a far greater level of collaboration is required than is currently enable. Significant structural health systems changes would be required. There is no evidence that such changes would be of benefit as the current primary maternity system is accessible and

<p>PHARMAC (61)</p>	<p>effective for pregnant woman. The concerns stated in our original submission in 2007 remain, that pharmacist prescribing in a primary maternity care environment has the potential to fragment care, as opposed to enhance it.</p> <p>Midwives acknowledge the valuable knowledge and experience that pharmacists have in relation to prescribing. We see that pharmacists have a crucial role to play in advising and supporting midwives in prescribing to ensure that the most effective and evidence based treatment are prescribed by them. Our view is that this advisory service is a role for pharmacists that could be expanded and developed in a community health context. Easier access to pharmacist expertise regarding best prescribing practice in a community setting would be a strategy that midwives would strongly support.</p> <p>In summary we continue to offer our cautious support to the concept of prescribing, but we are unclear how this could be of benefit to pregnant women within the current primary maternity services context.</p> <p><i>Implications for PHARMAC activity</i> - Our interest lies primarily with issues that are likely to arise from implementation of the proposed changes. This includes the cost of, and mechanisms for enabling, pharmacist provision of access to subsidised products on the Pharmaceutical Schedule – issues that relate to our activities but lie outside the scope of this consultation. We look forward to the Pharmacy Council's early engagement with PHARMAC, and other appropriate agencies, on these implementation issues to ensure they are mitigated or addressed.</p>
<p>Pharmaceutical Industry (54)</p>	<p>The RMI supports a health system that places the patient at the centre and where reform significantly improves the environment for the patient in a safe and efficient manner. While we support in principle pharmacists playing a greater role in providing access to medicines where such access is currently less than optimal, we are concerned that pharmacists' limited diagnostic capabilities may pose a risk to patients.</p> <p>The success of the proposal to allow pharmacist prescribing hinges on adequate safety systems being put in place. In addition, the success of the proposal requires that the doctor and pharmacist are working in concert to support the needs of the patient and the IT systems required to support this are not yet available.</p> <p>RMI submits that audit and monitoring requirements should be developed in concert with this proposal, to avoid major stumbling blocks during implementation.</p> <p>Both patients and pharmacists need to be protected from the possibility that prescribing could be influenced by profit margins. RMI believes PCNZ proposed controls to prevent this will add to expenses and are unlikely to be able to adequately control financial incentives altering prescribing practice.</p>
<p>Primary Health Organisation (36)</p>	<p>In principle CHWT doesn't oppose the application however it thinks it is important to strengthen the protection of patient safety and continuity of care by the following.</p> <p><b>Communication</b> The pharmacist prescriber must communicate directly in the patient's clinical record; this may be via remote access. Where this is not possible the communication must be by a Healthlink secure message that can be directly added to the patient's clinical record. In certain cases, for instance when a patient is in a fragile state, oral communication may also be required.</p> <p><b>Diagnosis</b> More emphasis must be placed on the pharmacist prescriber working with a diagnosis made by a medical doctor. An exception will be for minor ailments, especially when decision support tools exist.</p>
<p>Regulatory Authority – Health Professions (16)</p>	<p>Overall a very extensive and complete paper, logical, well-sequenced, with full background which enabled the reader to clearly follow the purpose, development and context. Due attention has been given to risks as well as benefits, and it is</p>

Regulatory Authority –  
Health Professions (34)

acknowledged any change must be in the interests of public health and safety. The scope is also supported by the background document's thorough descriptions of current pharmacist roles and overseas comparisons. However, it should be noted that physiotherapists do not have a prescribing scope of practice, and so have a limited point of reference.

A very thorough and thoughtful proposal. It clearly identifies the benefits to patients of extending the role of pharmacists and establishes the framework for ensuring competence amongst those holding the proposed scope. Pharmacists are clearly a major resource within the primary care team and the Osteopathic Council recognises the benefit to osteopathic patients of the creation of the Pharmacist Prescriber role. It is imperative that the health system maximises the use of the skills within the workforce.

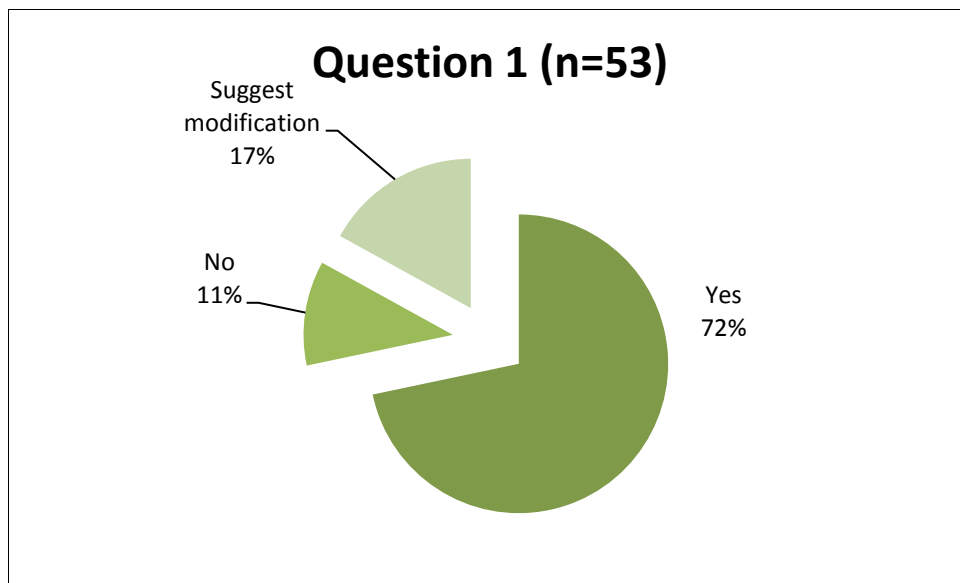
Regulatory Authority –  
Health Professions (57)

In July 2007 the Council responded to an earlier consultation on this subject by noting that Council members and staff are very pleased with the approach being taken by the Pharmacy Council on this important issue. We continue to be impressed with the thought and caution being taken by the Pharmacy Council. However, the Medical Council does have some concerns about the current proposals. In the council's view, the proposed scope, competency framework and accreditation standards should more explicitly restrict pharmacist prescribing to situations where they are working as part of an interdisciplinary team, and where a diagnosis has already been made and all team members are fully informed about prescribing decisions. MCNZ would have serious concerns about independent pharmacist prescribing outside this setting for a number of reasons.

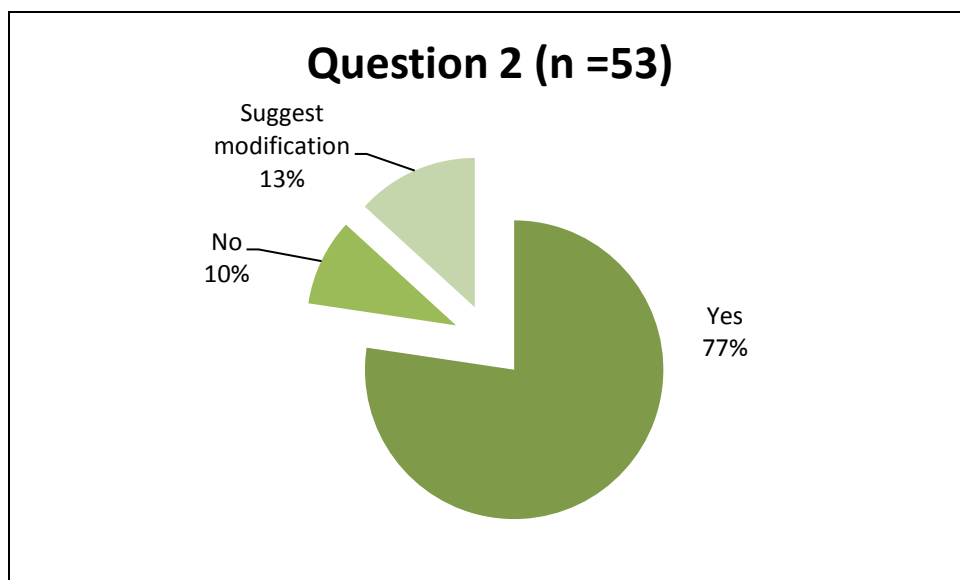
### Analysis 3 Responses to Questions Asked in the Consultation

Analysis 3 specifically considered the responses received for the series of questions that were asked in the consultation document and is presented accordingly. The graphs represent data from online submissions only (53/71) and are therefore representative of 75% of the total number of submissions received. The full analysis however in this section included responses received from both online and written submissions as applicable to the questions asked. The section describing Council’s response to the feedback received identifies the areas of modification.

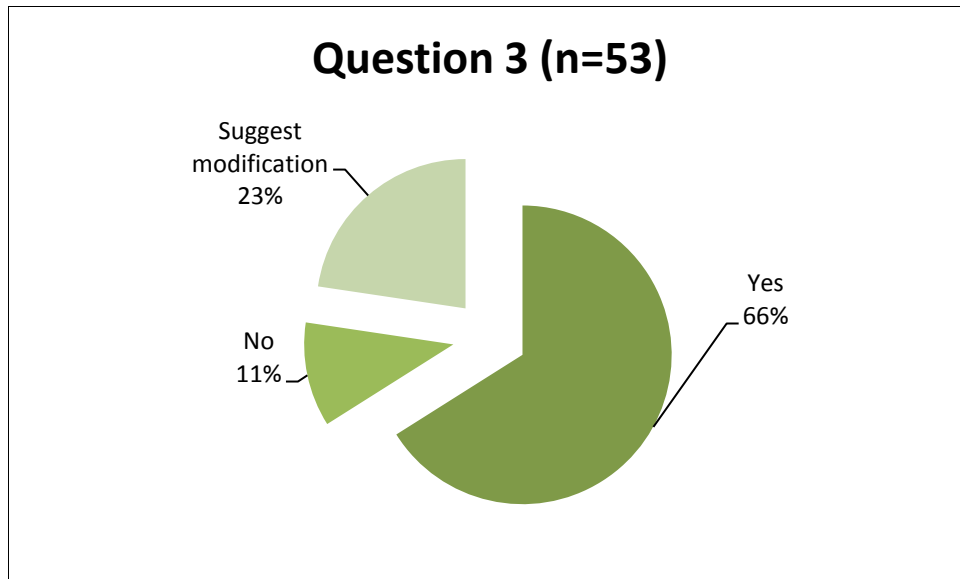
#### Question 1 Do you in agree with the proposed scope of practice definition – pharmacist prescriber?



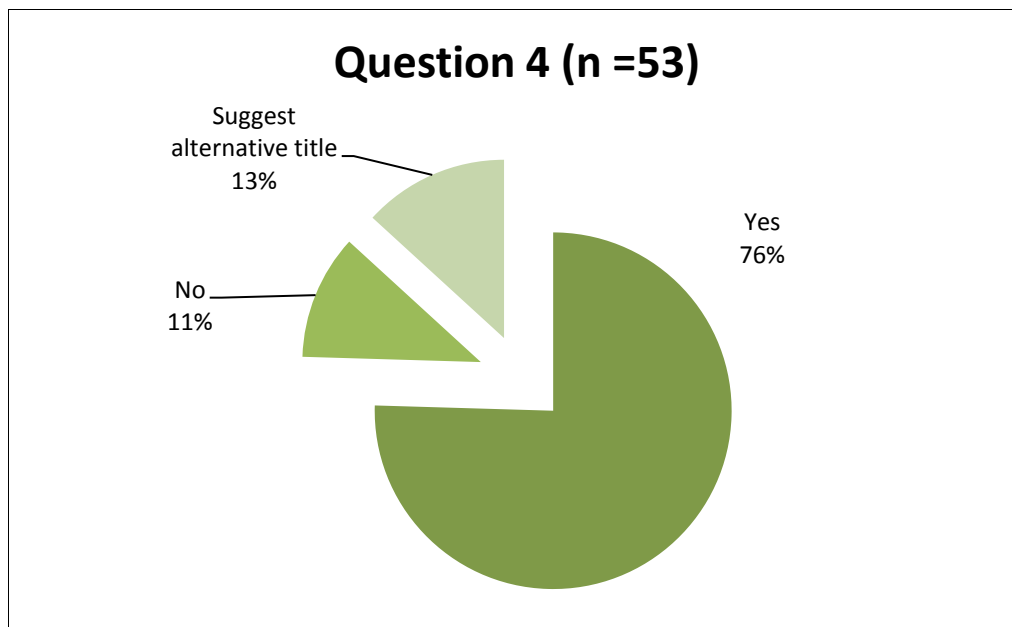
#### Question 2 Do you agree that the prescription medicines a pharmacist prescriber is able to prescribe be determined by the collaborative health team environment within which they will be practising? (p44 of the Consultation Document)



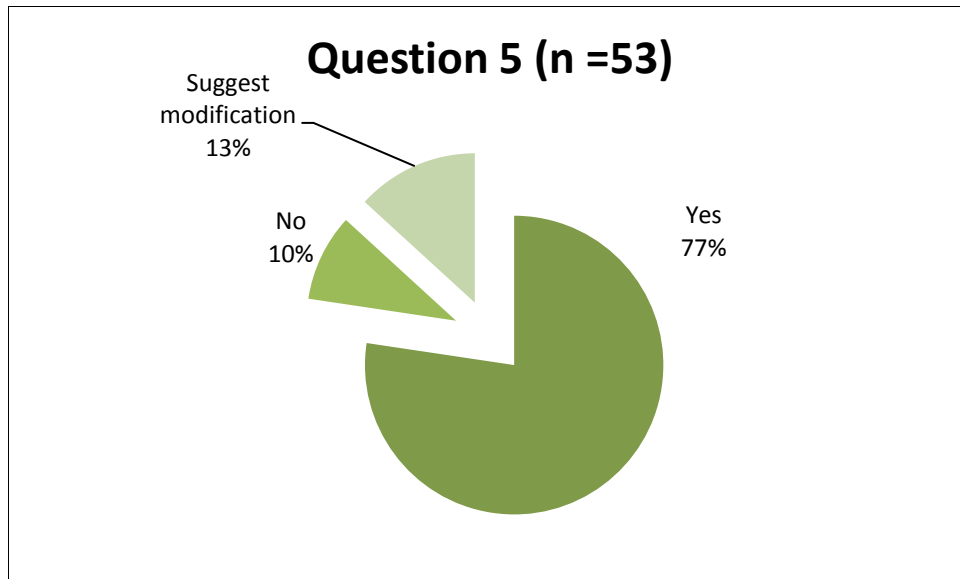
**Question 3 Do you agree with the identified exclusions? (p45 of the Consultation Document)**



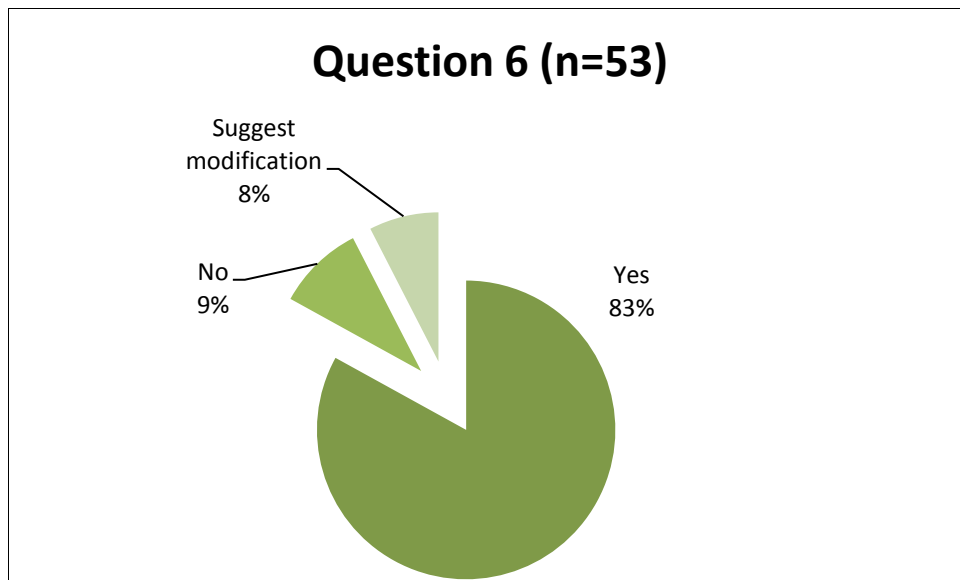
**Question 4 Do you consider the title 'Pharmacist Prescriber' is a title that will inform the public and other health professionals in the collaborative health team that a pharmacist is authorised to prescribe prescription medicines? (p46 of the Consultation Document)**



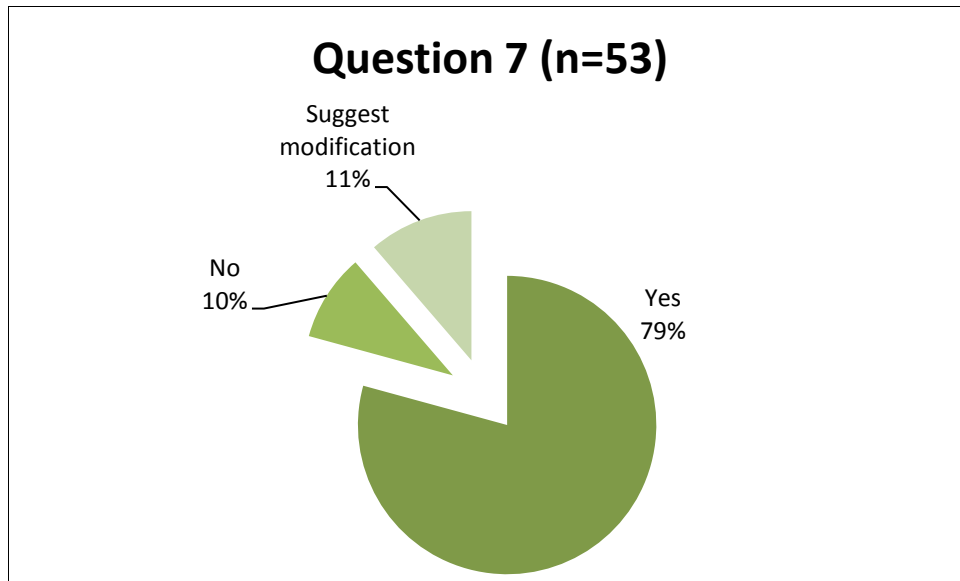
**Question 5 Do you agree with the competencies outlined in the competency area "The Consultation"?**



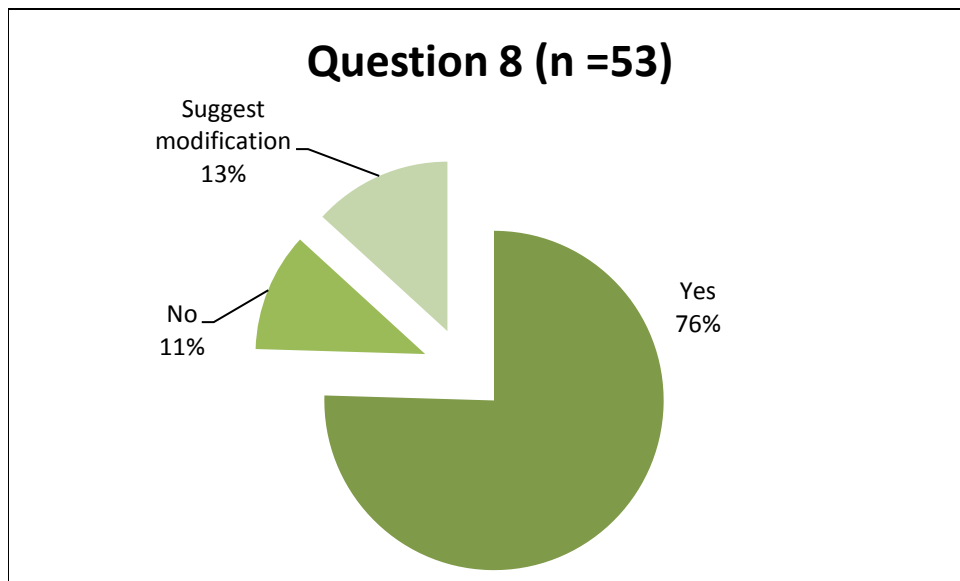
**Question 6 Do you agree with the competencies outlined in the competency area "Prescribing Effectively"?**



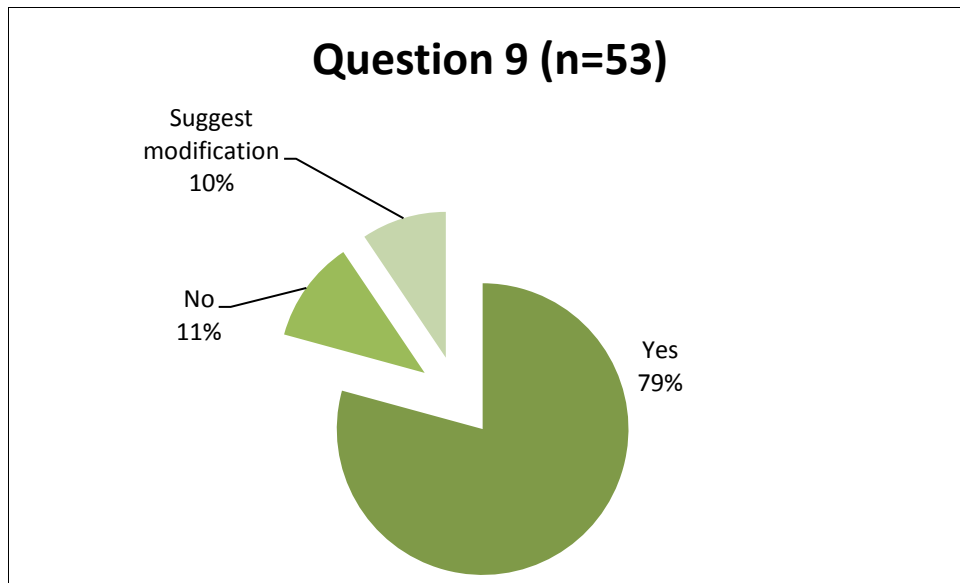
**Question 7 Do you agree with the competencies outlined in the competency area "Prescribing in Context"?**



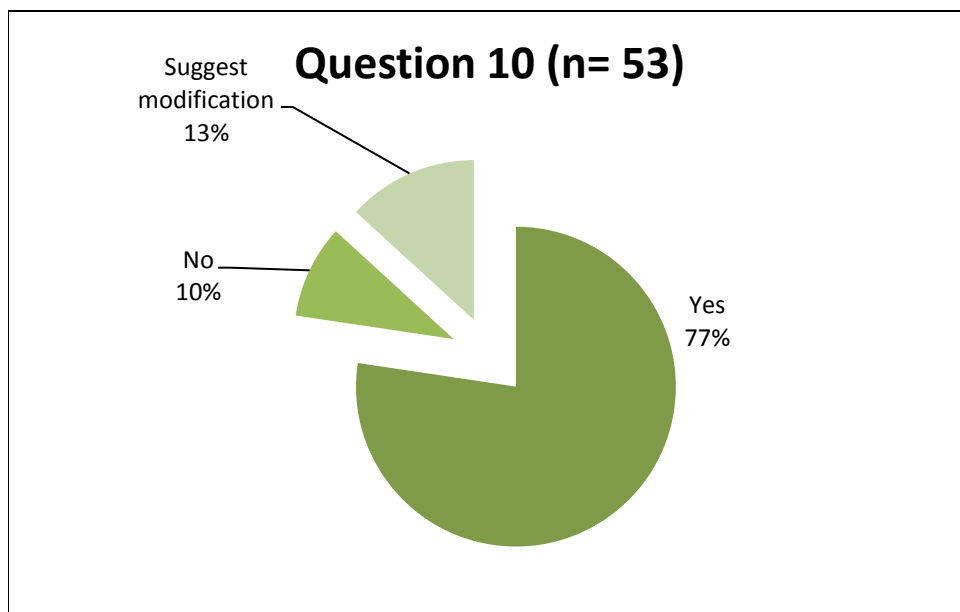
**Question 8 Do you agree with the four accreditation standards?**



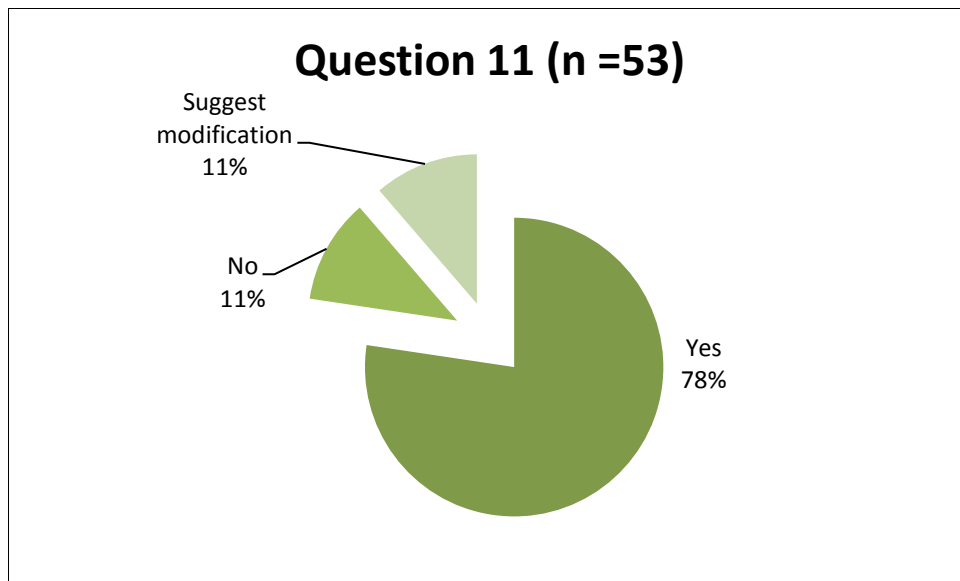
**Question 9 Do you agree with the proposed curriculum outline?**



**Question 10 Do you agree with the requirements for registration as a pharmacist prescriber? (outlined on p49 of the Consultation Document)**



**Question 11 Do you agree with the proposed requirements for ongoing competence and monitoring of pharmacist prescribers? (p50 of the Consultation Document)**



## Consultation Outcomes

The Council's approach to responding to concerns raised and/or suggested modifications in submissions is as follows:

- As a general rule, the proposal was amended if information or comments received:
  - provided new and relevant information that substantively impacts on the appropriateness and public safety requirements of the proposed scope of practice;
  - clarified or proposed an alternative that would better achieve proposed scope objectives; or
  - corrected errors or omissions.
- Similarly, some aspects of the proposal have not been amended if information or comments received:
  - contradicted aspects for the proposal for which there is general support in the healthcare sector in New Zealand;
  - were contrary to relevant legislation;
  - addressed matters beyond the scope of the consultation;
  - raised concerns that are not affected by the proposal or that are satisfactorily addressed by it; or
  - ignored or contradicted relevant established facts.
- Where there is no change to the initial proposal, this was either because no comment or additional information was received on that proposal; or because comments received did not necessitate a change.
- Where comments and information received have warranted a change, the proposal has been revised to reflect this change.

## Council Response – changes made to proposal post-consultation

Using the above approach to analyse the submissions received Council has made changes to a number of aspects of the proposal. These changes and clarifications are included in the application to Health Workforce New Zealand for independent prescribing rights for pharmacists.

### 1 The Pharmacist Prescriber scope of practice definition

#### Issue 1

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

#### Council Response

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

## Issue 2

Prescribing scope of a Pharmacist Prescriber with respect to diagnosis and initiation of therapy

### Council Response

Initiation of therapy by a Pharmacist Prescriber 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 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.

In summary:

- The current undergraduate training for pharmacists provides a foundation level of experience in diagnostic and clinical assessment skills.
- 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.
- 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).
- The majority of prescribing decisions made by Pharmacist Prescribers will be to continue and/or modify therapy.
- There will be some instances when a Pharmacist Prescriber will initiate therapy but they 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 .
- 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.
- 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).

### **Issue 3**

Communication of prescribing decisions and maintenance of clinical records

#### **Council Response**

Council has addressed issues relating to this by using the exemplars to demonstrate how pharmacists (in collaborative health team environments) currently communicate their decisions and recommendations and maintain 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 in the relevant prescribing competence standard.

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 the application are used to demonstrate the current communication and clinical record keeping practices of pharmacists currently working in collaborative health team environments.

### **Issue 4**

Strengthening the definition of a 'collaborative health team environment'

#### **Council Response**

Council has added to the definition to make it more robust and definitive and has specified the components of this type of environment (see over page). The Prescribing Competency Framework and registration requirements have also been amended to reflect this.

### **Key Components of a Collaborative Health Team Environment**

- 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.
- 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.

## 1.1 Revised Pharmacist Prescriber Scope of Practice Definition for Gazette notice

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 received valuable feedback regarding the proposed scope of practice definition for a Pharmacist Prescriber and has consequently revised the definition. The revised definition is presented below.

### Pharmacist Prescriber scope of practice (post consultation)

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.<sup>5</sup> 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<sup>6</sup>. 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 investigations 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.<sup>7</sup>

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

<sup>5</sup> Refer to key components of a collaborative health team environment mentioned earlier

<sup>6</sup> The Pharmacist Prescriber will not be the primary diagnostician.

<sup>7</sup> 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.

## 2 Classes of Medicines

Feedback from the consultation indicated a strong support for the Council's proposal *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*. This will be determined by the nature of the breadth of patients under their care and/or the focus of their clinical practice. 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. 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.

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.

The background information included in the 2010 consultation document 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.

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 qualification, 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.

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.

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. 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).

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.

### 3 Changes to Proposed Medicine 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.

#### 3.1 Controlled Drugs

In the consultation feedback, two respondents raised the issue of adding controlled drugs to the proposed exclusion list.<sup>8</sup> Council acknowledges the concerns expressed by these respondents who stated that Pharmacist Prescribers should not be able to prescribe 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 narcotics 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 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.

#### 3.2 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 prescribing them for the purpose of modification and continuation of therapy. Such exclusions could restrict the benefits and continuity of care to patients.

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.

##### **Exclusion 1**

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.

<sup>8</sup> A General Practitioner and the New Zealand Society of Anaesthetists

### 3.3 Prescribe unapproved/unregistered medicines restricted by sections 20 and 24 of the Medicines Act<sup>9</sup>

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.<sup>10</sup>

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.

### 3.4 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.

<sup>9</sup> 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

<sup>10</sup> 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).

## 4 Education and Competencies

In determining the competencies, additional education and training requirements 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. The consultation document provides a detailed background.

Feedback was sought on the prescribing competency framework and the accreditation standards for the qualification. The accreditation standards included a curriculum outline which set out the indicative content for the qualification.

### 4.1 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.

#### *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.

#### *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.

#### *Accreditation of the Qualification*

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*. These Standards were part of the consultation and feedback received has resulted in changes that clarify the intent of the Standards and the prescribing practicum including the role of the DMP.

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. Currently 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.

### 4.2 Prescribing Competency Framework and Curriculum

The prescribing competency framework consists of 3 broad areas and eight competence standards and has been used to inform the initial qualification curriculum of Pharmacist Prescribers. 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 (2<sup>nd</sup> edn, an 2009, revised Apr 2009)*. Both the prescribing competency framework and the curriculum were part of the consultation. Changes made to these ensure alignment with the revised scope of practice definition and practice within a collaborative health team environment.

In particular the curriculum recognises

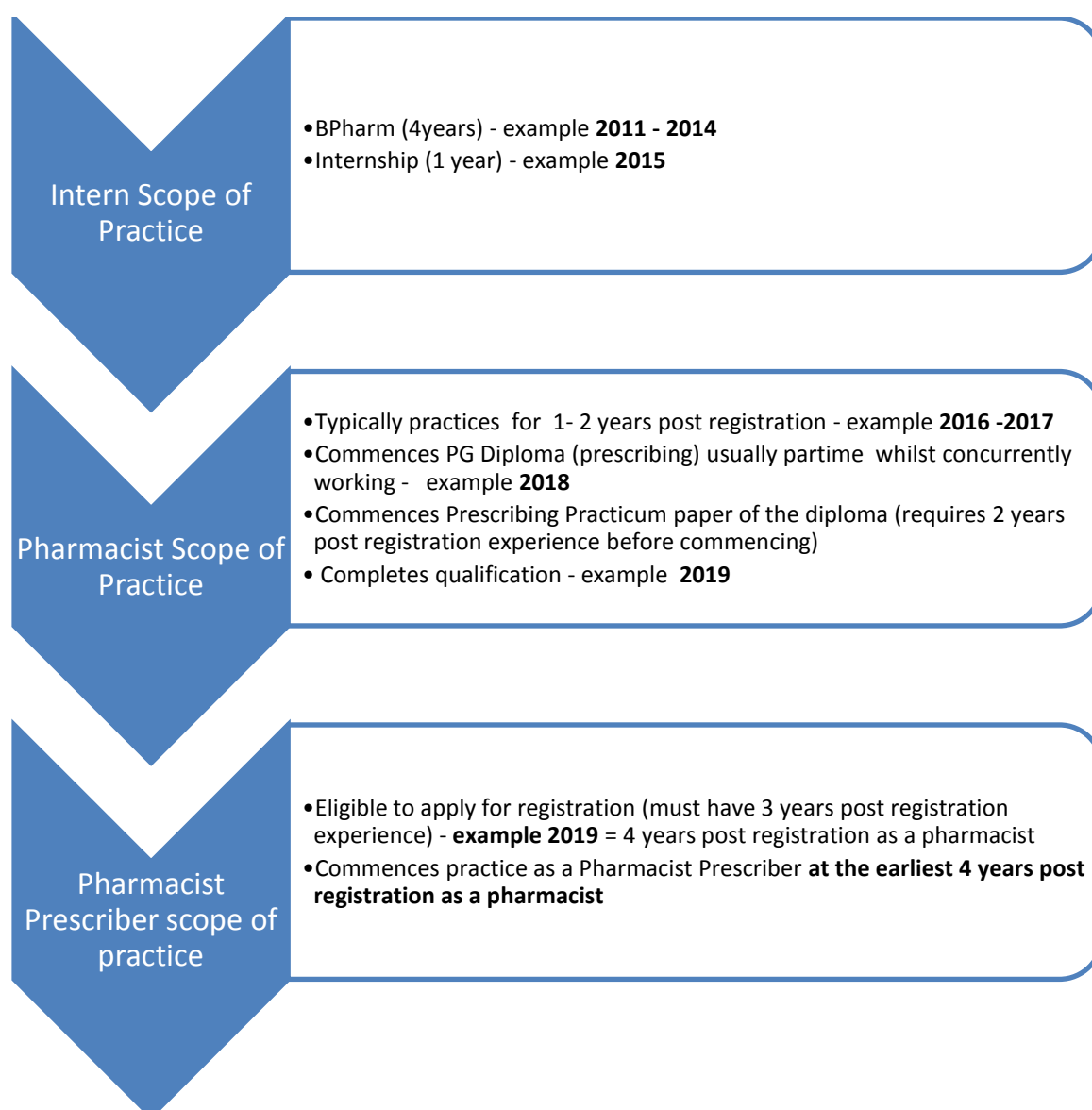
- The undergraduate training of pharmacists does provide for an excellent and extensive foundation in pharmacology, pharmacodynamics, pharmacokinetics, therapeutics, pharmaceutical sciences and social aspects of pharmacy.
- The undergraduate training of pharmacists does provide a foundation level of 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.
- 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.

#### 4.3 Education, Qualification and Registration Pathway for future Pharmacist Prescribers

Council considered the wide ranging views received in the consultation feedback on the length of the education and training requirements proposed. Council 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 National Health Service (NHS).

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 within the New Zealand healthcare system.

**Figure 2**



#### **4.4 Education, Training and Registration under the Recognition of Prior Learning and Experience (RPLE) Pathway**

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

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 already practising in a collaborative health team environment who may wish to pursue registration in the Pharmacist Prescriber scope of practice. This cohort of pharmacists are typically holders of (or in the process of completing) a post graduate Diploma or Masters level qualification in clinical pharmacy, 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.

Feedback from the consultation indicated that a separate but possible cohort of pharmacists also in this group may be those who have been trained, registered and have practised as independent prescribers outside of New Zealand. These pharmacists would predominantly be from the UK, Canada and the USA. Council has resolved that this group of pharmacists would have to first meet the registration requirements for 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 and map the prior learning and experience to the prescribing competencies, 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 proposed 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.

## 5 Clarification of 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 includes changes in response to the feedback received from the consultation.

### **5.1 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.

### **5.2 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**

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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.

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#### **Competence Standard 2**

##### **Contribute to the Quality Use of Medicines**

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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.

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#### **Competence Standard 4**

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## **Apply Management and Organisation Skills**

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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.

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### **Competence Standard 5 Research and Provide Information**

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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.

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#### **5.2 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.

#### **5.3 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.

#### **5.5 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. The same will be expected of a Pharmacist Prescriber.

## 6 Ongoing Competence (Recertification) Requirements

Feedback from the consultation indicated strong support for the proposed recertification requirements. No significant change was made to the proposal in relation to this. 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. In developing these guidelines Council will look at models to assess ongoing competency for other prescribers in New Zealand e.g. nursing, medical.

The guidelines will:

- require CPD to reflect their practice as prescribers. Pharmacist Prescribers would be expected to use the prescribing competency framework to identify their ongoing CPD learning needs.
- direct that CPD activities of Pharmacist Prescribers must be multidisciplinary and include a combination of clinical audits, peer reviews and a learning portfolio.

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) and would recognise credentialing system(s) conducted by employer organisations such as DHBs and PHOs.

## Appendix 1 Stakeholder Groups Advised of Consultation

### Pharmacy Profession

Practising Pharmacist – All ( e-mail notification individually and via pharmacy chat group postings)

Hospital Pharmacy Department - All

Maori Pharmacists Association (MPA)

Pharmacy Guild NZ (Inc)

Pharmacy Industry Training Organisation (PITO)

Pharmaceutical Society of New Zealand (PSNZ) (Inc)

EVOLVE Intern Pharmacist Training Programme

Clinical Advisory Pharmacists Association (CAPA)

New Zealand Hospital Pharmacists Association (NZHPA)

NZHPA Special Interest Group (SIG) – Mental Health

NZHPA SIG – Drug Information and Clinical Pharmacy

NZHPA SIG - Oncology

New Zealand College of Pharmacists (NZCP)

Pharmacy Defence Association (PDA)

Waikato Community Pharmacy Group

Canterbury Community Pharmacy Group

Pharmacy Brands

Pharmacy Partners

Radius Pharmacy Group

### Nursing Organisations

NZ Nurse's Organisation

Nurse Practitioner's Advisory Group

College of Nurses Aotearoa

### Other Health Professional Groups

NZ Dental Association

NZ College of Midwives

New Zealand Society of Podiatrists

Dietitians New Zealand Incorporated (Dietitians NZ)

New Zealand Association of Optometrists

New Zealand Society of Physiotherapists Inc

Allied Health Professionals Forum

### Medical Organisations

New Zealand Medical Association (NZMA)

General Practitioners' Council

Royal New Zealand College of General Practitioners (RNZCGP)

The Royal Australian and New Zealand College of Psychiatrists (RANZCP)

Australian and New Zealand College of Anaesthetists, New Zealand National Committee

Australasian College for Emergency Medicine

College of Intensive Care Medicine of Australia and New Zealand

New Zealand College of Public Health Medicine

Royal Australasian College of Surgeons

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

The Royal Australian and New Zealand College of Ophthalmologists

The Royal Australasian College of Physicians

The Royal Australian and New Zealand College of Radiologists

The Royal College of Pathologists of Australasia

New Zealand Rural General Practice Network

Paediatric Society of New Zealand

Accident and Medical Practitioners Association (AMPA)

Association of Salaried Medical Specialists

### Health Regulatory Authorities of New Zealand (HRANZ)

HRANZ - All

HRANZ Chair - All

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**Ministry of Health**

Health Workforce NZ

Medsafe

Medicines Control

Strategy and Systems Performance  
(previously Health and Disability Systems Strategy Directorate)

Programme Delivery  
(previously Sector Capability and Innovation)

National Health Board

**Ministry of Economic Development****Consumer Groups**

Consumer New Zealand

Grey Power

Age Concern New Zealand Inc

Asthma & Respiratory Foundation of New Zealand

Diabetes New Zealand

Health & Disability NGO (non-governmental organisation) Working Group

National Heart Foundation

**Other Relevant Interested Parties**

PHARMAC

Accident Compensation Corporation (ACC)

Health and Disability Commissioner (HDC)

**Academic/Teaching Institutions**

School of Pharmacy, University of Auckland

School of Pharmacy, University of Otago

School of Nursing, University of Auckland

School of Nursing, Otago Polytechnic

School of Nursing, Massey University

School of Medicine, University of Auckland

School of Medicine, University of Otago – Dunedin and Wellington campus

Department of Optometry & Vision Science, University of Auckland

Clinical Pharmacology Department, School of Medicine, Christchurch and Wellington

**Other Primary and Hospital Based Healthcare Providers/Organisations**

District Health Boards New Zealand (DHBNZ)

District Health Board (DHB) - All

Chief Medical Advisors Group

DHBNZ Safe and Quality Use of Medicines

BPAC (Best Practice Advocacy Centre)

IPAC (Independent Practitioner Association Council)

Hospice New Zealand

Eldernet

Hospital Palliative Care New Zealand

Pegasus Health

**Pharmaceutical Industry**

Researched Medicines Industry (RMI) – now known as Medicines New Zealand

New Zealand Self Medication Industry Association Inc

**International Stakeholders**

Pharmacy Board of Australia

Australian Pharmacy Council

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## Appendix 2 List of Respondents

Respondent Number	Respondent Detail	Professional Area of Practice
1	Lois Paton General Practitioner	Medical - General Practice
2	Pharmacy Department Wellington Hospital	Pharmacy - Hospital
3	Dianne Vicary Community Pharmacist Vicary Pharmacy Services Ltd	Pharmacy - Community
4	Pharmacy Department North Shore & Waitakere Hospitals	Pharmacy - Hospital
5	Pharmacy & Therapeutics Committee, Director of Allied Health, Director of Nursing, Waitemata DHB	DHB
6	Robbie Hannon Community Pharmacist Waimuku Village Pharmacy Ltd	Pharmacy - Community
7	Carolyn Woolerton Pharmacist	Pharmacy - Clinical Advisory Pharmacist
8	Glenn Roberts Community Pharmacist	Pharmacy - Community
9	Rae Lamb Acting Health and Disability Commissioner	Other - HDC
10	Anne Denton Pharmacist	Pharmacy - Pharmacist Facilitator palliative Care
11	Permission not given	Pharmacy - Hospital
12	Katrina Tandeki Hospital Pharmacist	Pharmacy - Hospital
13	Miguel Carbajal Guerrero Community Pharmacist	Pharmacy - Community
14	Hjg Hospital Pharmacist	Pharmacy - Hospital
15	Combined PHO Clinical Board Mid Central Health	PHO
16	Physiotherapy Board of New Zealand	Regulatory Authority
17	Dietitians New Zealand	Other Health Professional Group
18	Physiotherapy New Zealand	Other Health Professional Group
19	Robin Norvill Community Pharmacist Wairoa Pharmacy	Pharmacy - Community
20	Laurence Metry	Pharmacy - Community
21	Ian Ternouth Medical Specialist	Medical - Cardiologist
22	Permission not given	Medical - Specialist
23	Richard Steele Medical Specialist	Medical - Clinical Immunologist, Immunopathologist, Senior Lecturer
24	Jo Mickleson Community Pharmacist	Pharmacy - Community
25	Permission not given	Medical - Specialist
26	Permission not given	Medical - Specialist
27	Angela Blackwood Pharmacist	Pharmacy - Independent Contractor
28	Permission not given	Medical - health centre
29	Permission not given	Medical - General Practice
30	Angus Chambers General Practitioner	Medical - General Practice
31	Elizabeth Lesley Hawke Hospital Pharmacist	Pharmacy - Hospital
32	Permission not given	Pharmacy - Hospital
33	School of Nursing University of Auckland	Academic/Teaching Organisation
34	Osteopathic Council of New Zealand	Regulatory Authority
35	Accident and Medical Practitioners' Association (AMPA)	Medical - Hospital emergency departments and community clinics

36	Compass Primary Healthcare Network	PHO
37	Murray Foreman Pharmacist	Pharmacy - primary/secondary interface pharmacist
38	Vanessa Brown Pharmacist	Pharmacy - palliative care, hospice
39	Mahabat Rasoul Community Pharmacist	Pharmacy - Community
40	Reshma Gilbert	Pharmacy - Community
41	Pharmacy Guild of NZ (inc)	Pharmacy Organisation
42	Permission not given	Pharmacy - Hospital
43	School of Pharmacy, University of Otago	Academic/Teaching Organisation
44	Kerri Miedema Community Pharmacist	Pharmacy - Community
45	Julie Kilkelly Community Pharmacist	Pharmacy - Community
46	Alice Littlewood Community Pharmacist Pharmacy 547	Pharmacy - Community
47	Mental Health Special Interest Group of the NZHPA	Pharmacy Organisation
48	Chris Jay Hospital Pharmacist	Pharmacy - Hospital
49	Brendon Jiang Community Pharmacist	Pharmacy - Community
50	Te Ao Maramatanga - New Zealand College of Mental Health Nurses	Nursing Organisation
51	College of Nurses Aotearoa NZ	Nursing Organisation
52	Clinical Services Directorate, ACC	Other - ACC
53	New Zealand Nurses Organisation (NZNO)	Nursing Organisation
54	Researched Medicines Industry (RMI) – now known as Medicines New Zealand	Pharmaceutical Industry
55	Clinical Advisory Pharmacists Association (CAPA)	Pharmacy Organisation
56	New Zealand Medical Association (NZMA)	Medical Organisation
57	Medical Council of New Zealand (MCNZ)	Regulatory Authority
58	Royal Australian & New Zealand College of Psychiatrists (RANZCP)	Medical Organisation
59	Permission not given	Midwifery organisation
60	Pharmaceutical Society of New Zealand (PSNZ)	Pharmacy Organisation
61	PHARMAC	Funding Authority
62	Clinical Advisory Board Auckland District Health Board	DHB
63	Pharmacy Department, Auckland District Health Board	Pharmacy - Hospital
64	The Royal Australasian College of Physicians & The Cardiac Society of Australia and New Zealand	Medical organisation
65	Permission not given	Medical Organisation
66	The Royal New Zealand College of General Practitioners (RNZCGP)	Medical Organisation
67	20 DHBs collective submission	DHBNZ
68	Clinical Board, Wairarapa DHB	DHB
69	New Zealand Society of Anaesthetists (NZSA)	Medical Organisation
70	Permission not given	Medical - General Practice
71	New Zealand Hospital Pharmacists' Association (NZHPA)	Pharmacy Organisation

## Appendix 3      Extended Consultation with Consumer and Māori groups

The following groups and individuals were initially advised of the consultation on the Pharmacist Prescriber scope of practice. Feedback was not received from these groups during the initial 6 week consultation period. The Council directed that these groups should be contacted again and offered another opportunity to provide feedback. They were contacted individually and sent a cover letter including the preliminary results of the consultation and the consultation document. The time frame to respond the second time was 5 working days.

### 1. Consumer Groups

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#### Consumer Groups Invited to respond a second time

Age Concern New Zealand – no response received

Asthma and Respiratory Foundation – no response received

Consumer New Zealand – no response received

Diabetes New Zealand – no response received

Grey Power – no response received

National Heart Foundation of New Zealand – see response below

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**Responses Received:** Diabetes NZ and the Asthma and Respiratory foundation had indicated at the time of contact that they would not be able to respond within the time frame given.

A response was received from the National Heart Foundation (see below).

The Pharmacy Council of New Zealand, the regulatory body for pharmacists, is proposing a new scope of practice for pharmacists. This new scope will allow suitably trained and qualified clinical pharmacists working in a collaborative health team environment to prescribe prescription medicines and controlled drugs to patients under their care.

I have read the documentation related to this proposal which is fully explanatory and detailed.

I strongly support the proposed new scope of practice given the training and accreditation requirements described and particularly the intended collaborative team approach.

I have lectured Pharmacy students since the inception of the Auckland programme and in recent years have continued clinical work as a physician in a secondary care setting where the local hospital pharmacists already make valuable contributions as team members. I think suitably qualified clinical pharmacists can have a more prominent and responsible role in the future and assist provision of high quality and effective care more widely. The role should not be limited necessarily to the clinical arena but should also extend to broader professional contributions related to clinical effectiveness, quality improvement and the development of guidelines, protocols and care pathways, again as team members.

Norman Sharpe ONZM MD FRACP FRSNZ  
Emeritus Professor  
Medical Director  
Heart Foundation  
Via e-mail Wed 29/09/2010

## 2. Māori Groups

Apart from the Māori Pharmacists Association, the individuals and groups listed here were invited to provide feedback on the proposed scope of practice for the first time. Like the consumer groups they were contacted individually, sent a cover letter including the preliminary results of the consultation and the consultation document. The time frame to respond was 5 working days.

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### Maori Groups/Individuals Invited to respond

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Maori Pharmacists Association (MPA)<sup>11</sup>

Bridget Robson, Ropu Rangahau Hauora a Eru Pomare, Wellington School of Medicine

Dr Donna Cormack, Ropu Rangahau Hauora a Eru Pomare, Wellington School of Medicine

Dr John Waldon, Research Centre for Maori Health Research and Development, School of Public Health Massey University

Dr Ricci Harris Ropu Rangahau Hauora a Eru Pomare, Wellington School of Medicine

Mr Bevan Clayton-Smith, Ngati Maniapoto, M Clin Pharm, PhD candidate, Research Centre for Maori Health and Development, Massey University

Te Ora : The Maori Medical Practitioners Association

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Dr John Waldon and the MPA president had indicated at the time of contact that they would not be able to respond in the given time frame.

No other responses were received.

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<sup>11</sup> This group was invited to respond for a second time