Feedback sought by 20 January 2016:

Draft options for the regulation of prescribing and dispensing in New Zealand

OUTLINE OF PAPER

1. The Medicines Act 1981 and its Regulations are being repealed and replaced. This paper provides some background information and outlines the process for an exposure draft of a new Therapeutic Products Bill in 2016.

2. Part A describes why medicines (or therapeutic products) need regulating and outlines the current regulatory arrangements that establish who can prescribe and dispense prescription medicines in New Zealand.

3. Part B describes the new approach to legislative design followed by some early draft options concerning the regulation of prescribing and dispensing on which feedback is sought. These proposals concern the shape of the primary legislation with respect to prescribing and dispensing. Consultation on the supporting regulatory detail will be ongoing throughout 2016.

INTRODUCTION

4. Medicines, medical devices, and cell and tissue therapies (and hybrids thereof) are collectively known as therapeutic products and they aim to treat or prevent ill health in humans. All developed countries regulate these products across their lifespan to ensure, as far as possible, that the benefits of their use outweigh the risks.

5. Since the early 1990s there have been attempts to address problems and weaknesses with New Zealand's regulatory regime and in late 2014, concurrent with announcing the cessation of work on Australia New Zealand Therapeutic Products Agency (ANZTPA), the New Zealand Government announced that work would commence on a new comprehensive regime to replace the Medicines Act 1981 and its Regulations.

6. The new regime is being designed to meet the needs of the health and disability support sector now and into the future and will be informed by the global settings for therapeutic products.

7. There will be a range of opportunities and methods for the public and sector to inform this process. An exposure draft of a Therapeutic Products Bill will be released for public consultation in mid-2016. This process enables an early draft of the Bill to be improved based on public and sector feedback ahead of the introduction of the Bill to Parliament. The exposure draft of the Bill will be accompanied by a description of the likely content of the regulations and subordinate instruments.

8. The Bill is expected to be introduced to Parliament at the end of 2016, and will then pass through the parliamentary process in 2017. Development of the regulatory detail to support a new Therapeutic Products Bill will be ongoing throughout 2016 and we will continue to engage with the public and sector during this time. The Ministry of Health website will have updates on this work as it progresses.

PURPOSE

9. This purpose of this paper is to seek feedback on some early draft options concerning the regulation of prescribing and dispensing of medicines/therapeutic products in New Zealand. Your feedback will help to inform components of the exposure draft of the new Therapeutic Products Bill.

10. The proposals below address the shape of the primary legislation with respect to prescribing and dispensing, with the development of supporting regulatory detail and subordinate instruments to be ongoing throughout 2016.

11. Please take the time to consider the proposals and provide your feedback. Questions are inserted throughout and are collated in the Appendix. Please send your responses to **Angela_Mansell@moh.govt.nz by 20 January 2016**.

PART A: BACKGROUND AND CONTEXT

CURRENT ARRANGEMENTS

12. Medicines are not ordinary items of commerce due to the potential for serious harm. Medicines are made available to the public under rules set out in legislation (currently the Medicines Act 1981 and Medicines Regulations 1984) designed to ensure that effective products are used safely and in accordance with licensed indications for use.

Classifications of medicines/therapeutic products

13. Medicines are assigned to legal classifications that establish the rules concerning the use of, and access to, each class of medicine (ie. whether a medicines should only be available via a health practitioner).

14. Classification decisions for medicines/therapeutic products are significant because they have a material bearing on consumer access to products, revenue (for prescribers, pharmacists and retail outlets), and costs to the health system.

15. There are three legal classifications of medicines under the current Medicines Act 1981, grouped according to potency, risk of adverse side effects and the need for the supply to be professionally supervised. Medicines not classified are referred to as general sale medicines and may be sold from any outlet. The three legal classifications are:

    i. Prescription medicines - may be supplied only on the prescription of an authorised prescriber (as defined in the Medicines Act 1981).

    ii. Restricted (or pharmacist only) medicine - may be sold without a prescription, but the sale must be made by a registered pharmacist, in a pharmacy, and details of the sale recorded.

    iii. Pharmacy-only medicine – may only be sold in a community or hospital pharmacy, or a shop in an isolated area that is licensed to sell that particular medicine. The sale may be made by any salesperson.

16. Classification is a significant issue and the parameters (and process for making classification decisions) will be tested as part of the exposure draft of the Therapeutic Products Bill in 2016.

Prescribing

17. The act of prescribing a medicine is part of a process which starts with the overall clinical assessment of a person who presents for preventive care or for treatment. Treatment may or may not include a full diagnosis and a clinical judgement about the most appropriate management of the condition, including the prescription of any medicine/s. Any management of care or care plan must take into account all relevant aspects of the patient's condition, and requires knowledge of the implications of any co-existing conditions and possible interactions with existing medication.

Dispensing

18. Dispensing is defined in the Medicines Act 1981 as:

    (a) the preparation of that medicine for sale to the public (whether in response to the issue of a prescription or a request by an individual to be supplied with the medicine); and

    (b) the packaging, labelling, recording, and delivery of that medicine

19. The act of dispensing also encompasses a number of other functions (eg, checking the validity of the prescription, the appropriateness of the medicine for an individual patient and

assembly of the product). In common usage "dispense" usually refers to the activity of pharmacists and dispensing doctors.

WHO CAN PRESCRIBE AND DISPENSE IN NEW ZEALAND

Categories of prescriber

20. Only certain health practitioners can prescribe prescription medicines. The current Medicines Act 1981 and Medicines Regulations establish three categories of prescriber, a brief overview is outlined in the table below with further detail following.

Category of prescriber	Health practitioners	Description
Authorised	Named in primary statute: Practitioners (ie. Medical practitioners, Dentists), Nurse practitioners, Midwives, Optometrists	• Prescribe independently • Prescribe medicines within scope of practice
Designated	Established by regulations: Diabetes nurse prescribers, Pharmacist prescribers, Dietitians	• Prescribe independently • Prescribe medicines within scope of practice from a list of permissible medicines
Delegated	Future groups as approved by Minister of Health. Currently there are none.	• Prescribe under the authorisation of an authorised prescriber who is not a designated prescriber • Prescribe in accordance with a delegated prescribing order (which must specify the medicines, the circumstances in which, and the people to whom, they may prescribe)

21. Under the current arrangements an authorised prescriber (including a designated prescriber) may only prescribe a prescription medicine in accordance with all conditions (if any) stated

in, the authorised prescriber's scope of practice (as determined by an authorisation granted under section 21 of the Health Practitioners Competence Assurance Act 2003)

22. A designated prescriber may only prescribe a prescription medicine if the prescription medicine is listed in regulations; and the requirements specified in or imposed under those regulations are satisfied. An overview of the regulatory detail is provided in the table below.

Regulations	Requirements specified in regulations
• Medicines (Designated Pharmacist Prescribers) Regulations 2013 • Medicines (Designated Prescriber – Registered Nurses Practising in Diabetes Health) Regulations 2011 • Medicines (Designated Prescriber – Dietitians) Regulations 2015	Before prescribing prescription medicines, a designated prescriber must have: • Obtained the qualification specified in the Gazette notice[1] (ie. the published scope of practice) • Completed the training as specified in the Gazette notice • Completed an assessment of competence as specified in the Gazette notice • Must be authorised by the Responsible Authority to practise and prescribe within the relevant scope of practice • It is an offence to do so otherwise (punishable on conviction by a fine not exceeding $500).

23. A delegated prescriber is a health practitioner to whom a delegated prescribing order has been issued. A delegated prescribing order is a written instruction, issued in accordance with regulations by an authorised prescriber, authorising a health practitioner to prescribe prescription medicines. While no detail in regulations has ever been drafted as to the delegated prescribing orders, the intent is that the order would set specific conditions and restrictions on prescribing (such as only certain medicines for certain patients) for an individual delegated prescriber. The competence, training and qualifications required of delegated prescribers would be set in consultation with the relevant Responsible Authority.

[1] Under the Legislation Act 2012, legislative instruments are to be published in the New Zealand Gazette (the official Government newspaper and authoritative journal of constitutional record).

Other regulatory mechanisms

24. Some prescription medicines are controlled under the Misuse of Drugs Act 1975 and Regulations 1977. The prescribing and dispensing of controlled drugs is more tightly controlled than for other medicines[2], reflecting the need to restrict access to, and minimise the misuse of controlled drugs. It is worth noting the Misuse of Drugs Regulations 1977 will be reviewed in 2016 and this work will occur in alignment with the development of the regulatory detail of the therapeutic products regime.

25. The regulation of health practitioners is covered by the Health Practitioners Competence Assurance Act 2003. The principal purpose of the HPCA Act 2003 is to protect the health and safety of the public and the HPCA Act 2003 contains the necessary provisions concerning the roles and functions of Responsible Authorities, scopes of practice, qualifications, competence and fitness for registration for regulated health professionals to ensure that practitioners are competent and fit to practise their professions for the duration of their professional lives.[3]

26. The Minister retains some important powers under the HPCA Act – to designate health professions for regulation, to establish new Responsible Authorities, to audit Responsible Authorities, to appoint or remove authority members, to determine mechanisms to facilitate resolution of disputes over scopes of practice and to gazette restricted activities that can be performed only by regulated health practitioners.

Interface with subsidised medicines

27. In New Zealand a range of medications are subsidised by the government. The rules that govern how the public access subsidised medicines are established by the Pharmaceutical Management Agency (PHARMAC) – a crown entity under the Crown Entities Act. These rules are not established in legislation and are set out in the New Zealand Pharmaceutical Schedule.

28. With some exceptions, any registered medical practitioner is legally able to prescribe any drug, however the subsidy may be targeted at certain patient groups. PHARMAC uses

[2] The tighter restrictions include limits to how long controlled drugs can be prescribed for, the use of secure electronic prescribing or triplicate controlled drug prescription forms, a requirement to dispense within a certain time from the prescribing date and the retention of information on dispensed controlled drugs for four years. Prescribing for the treatment of dependency is also subject to particular controls, with the Minister of Health retaining the power to specify (by Gazette notice) which medical practitioners and services can prescribe for the treatment of addiction.

[3] Not all health professions are regulated under the HPCA Act 2003. Some are not regulated because they pose little risk of harm to the public; some are not regulated because they work under the supervision of a regulated profession and some are regulated in other ways (eg. they may be regulated through their employer or self-regulated by their profession).

several mechanisms to target medications at certain patient groups. This includes prescribing guidelines, specialist only prescribing or recommendation, endorsements and Special Authorities (the Pharmaceutical Schedule contains this information).

STRATEGIC OBJECTIVES

29. A new regulatory regime needs to both reflect the needs of modern clinical practice as well as accommodate future pressures and shifting contexts. Demographic trends, technology advancements and changing public expectations influence the need for new models of care and service delivery, workforce utilisation and distribution, as well as growth in prescribing and changing prescribing roles.

30. The regulatory framework that supports prescribing and dispensing needs to be enabling and responsive to changing health needs and current and future prescribing groups, with controls calibrated to the risk of the activity. Any proposed changes need to bring about benefits to patient care, result in improved health outcomes, or equivalent health outcomes with improved patient convenience or more appropriate professional practise.

31. A future focused regulatory regime for prescribing and dispensing should support the following objectives:

Outcomes	Objectives
Quality, safety and efficacy	Ensures high quality care without compromising patient safety Improves health outcomes for patients Ensures accountability is appropriate and transparent
Access	Enables patients to obtain the medicines they need in a timely way Supports patient choice and convenience where possible
Optimal use	Makes best use of the skills of health practitioners Supports a collaborative approach between health practitioner and patient and shared decision making Minimises medicines waste

PART B: OPTIONS FOR DISCUSSION

32. The following section presents some options or proposals concerning the shape of the primary legislation with respect to prescribing and dispensing. Questions for consideration are included, however, you are invited to comment on any element of the following.

LEGISLATIVE DESIGN

33. The intent is that the new therapeutic products regulatory regime will be an enabling framework that can be readily maintained and updated. One of the key problems with the Medicines Act 1981 is that it has failed to keep pace with changing health needs, workforce development and evolving practice, mainly due to the amount of prescriptive detail contained in the primary statute.

34. What is proposed is a lean, principles-based Act containing only the central regulatory requirements, with details contained in regulations and subordinate instruments. This approach is strongly recommended by the Productivity Commission following its review of Regulatory Institutions and Practices. The review found that, across government, regulators were working with dated legislation and that the inappropriate placement of detail in primary legislation was a key driver of this problem.

35. The legislative design should also support clarity of regulatory roles and objectives. With respect to prescribing, the legislative framework should ensure role clarity between the therapeutic products regulator to ensure the quality and safety of therapeutic products across their life span, and the occupational regulatory role of Responsible Authorities regarding the competence and practise of regulated health practitioners.

CONDITIONS OF PUBLIC ACCESS TO THERAPEUTIC PRODUCTS

36. The classification of a therapeutic product is the process of specifying conditions on availability, for example, whether a product should only be available via a health practitioner. Currently classification applies to medicines which, on approval, are classified as prescription, restricted (pharmacist-only), pharmacy-only or for general sale.

37. Classification may need to apply to other types of therapeutic product over time and this should be enabled through the legislative arrangements. It is proposed that:

- the principles of medicines classification be adapted to apply to all therapeutic products and that these be set out in legislation
- legislation enables regulations to be made that set out additional precision specific to product types (eg, prescription medicine)

- legislation enables the regulator to set out any further detail in regulator-made instruments (eg, guidelines).

38. Given the significance of therapeutic product classification decisions it is also proposed the legislation require the regulator to establish a technical advisory committee to inform classification decisions.

39. It is proposed that the exposure draft of the Therapeutic Products Bill will set out the conditions by which the public are able to access therapeutic products in general terms, rather than using medicine-specific language. For example - general sales items will be freely available for sale. Other items will be only be available to the public under a set of conditions that could include the need for a written authority from an authorised person, availability only from a specified place, or from a specified person.

40. To ensure technical accuracy, the legal definitions of all necessary and relevant terminology (eg, therapeutic product, therapeutic purpose, authorised prescriber, administer, supply etc.) will also be consulted on as part of the exposure draft of the Therapeutic Products Bill.

AUTHORISED AND DESIGNATED PRESCRIBERS

Issues with the current regulatory approach

41. The main issues raised to date with the current regulatory arrangements that establish authorised and designated prescribers include:

- Authorised prescribers are named by practitioner grouping in primary statute. This has caused significant delays to keeping a current regulatory regime.
- A list of medicines may not be an effective regulatory tool for defining a scope of practice as relates to prescribing for some practitioners. For example, the list of medicines for Pharmacist prescribers is over 1500 in number.
- Designated prescribers are defined as authorised prescribers in the primary statute, but work within particular scope of practice conditions regarding their prescribing. In principle <u>all</u> prescribers work within particular scope of practice conditions, therefore, translating this approach into a refreshed regulatory arrangement not be required.

Options to address the current issues

42. In a new regulatory regime the issues identified above could be partially addressed by ensuring:

- authorised prescribers are not named by practitioner title in primary statute and

- prescriptive detail is used in subordinate legislative instruments so that updates can occur in timely way.

43. A different approach to the regulation of prescribing is covered in some detail below for you to consider.

44. It is proposed that the following fundamental principles should govern the authorisation of prescribing:

- a practitioner who is authorised to prescribe must be a registered health practitioner under the meaning of the HPCA Act 2003, and
- a practitioner must only prescribe therapeutic products within her/his scope of practice and competence (scopes of practice must be specified by Responsible Authorities under Section 11 of the HPCA Act), and
- Responsible Authorities have the statutory accountability for establishing scopes of practice, prescribing the qualifications necessary for registration within that scope, and for the ongoing competence and activities of their registered health practitioners.

45. If we accept the principles above, then it becomes apparent we could shift the authorisation of who is entitled to prescribe (including any necessary parameters within which practitioners may prescribe) to Responsible Authorities regulating health practitioners under the HPCA Act 2003. Detail identifying the authority to prescribe would therefore be included in the scopes of practice published by Responsible Authorities.

46. There are already existing scopes of practice that contain a level of detail considered sufficient to authorise prescribing. The Nurse Practitioner scope of practice is one such example (see www.nursingcouncil.org.nz/Nurses/Scopes-of-practice/Nurse-practitioner).

47. The current requirement for practitioners who are designated prescribers to prescribe within particular conditions (such as prescribing under supervision or as part of a team environment and/or the requirement to prescribe from a list of permissible medicines) could readily be included in scope of practice detail to authorise prescribing (largely this information is already included in relevant, published scopes of practice).

Example scope of practice outline to authorise prescribing:

- An overview description of the scope of practice
- Reference to the qualifications required for registration in the scope of practice
- A statement that those who meet certain requirements are:
    - authorised to prescribe prescription medicines/therapeutic products within their specific area of practice
    - able to authorise a Standing Order
- Any requirements relating to demonstration of specified competencies for entry into scope of practice, or any continuing competence requirements

Additional inclusions for those currently defined as designated prescribers:

- Any additional training and qualifications required for practitioners that prescribe (if not all registered practitioners working within the general scope are entitled to prescribe)
- Any additional conditions on prescribing ability, for example:
    - prescribes under supervision or as part of a team environment
    - prescribes from within a list of medicines published by Gazette notice (the list may contain further restrictions as relates to use, route of administration or pharmaceutical form).

Questions for consideration:

- Are there other issues with the current regulatory arrangements that establish authorised and designated prescribers?
- Do you have any comments concerning the principles that govern the authorisation of prescribing in paragraph 44?
- Given the example outline above, are there further details needed in a scope of practice to authorise prescribing or to authorise the ability to issue a Standing Order?

Advantages

48. The advantages of the above approach are that:

- the prescribing authority and any conditions/parameters on prescribing could be updated readily without waiting for legislation to be amended
- it aligns more appropriately with regulatory roles and functions (and ensures role clarity) between the therapeutic products regulator (for the quality and safety of therapeutic products throughout their lifespan) and the jurisdiction of Responsible Authorities for the practise of registered practitioners[4]
- the HPCA Act 2003 already contains specific provisions to govern scopes of practice, such as:
    i. health practitioners must not work outside their scope of practice
    ii. Responsible Authorities must consult with all affected parties before publishing a scope of practice by Gazette notice
    iii. the qualifications for a scope of practice must also published by Gazette notice.
- it would avoid duplicating the scope of practice, qualifications and competence detail in a legislative instrument under the Therapeutic Products Bill.

Approval of a new scope of practice or a significant change to a scope of practice

49. Under the approach outlined above the process for establishing a new group of prescribers would not need to change. In the broadest terms this process requires that first a service need be identified. Responsible Authorities then establish, through a period of consultation, the appropriate parameters of prescribing activity (and the associated training and qualifications needed). Health Workforce NZ then considers the proposal in line with the strategic objectives of the health system, and the Minister of Health makes a decision whether to approve.

50. In the past, a significant change to a scope of practice (when a practitioner group has changed from designated prescribers to authorised prescribers) has involved the same steps as above.

[4] The accountability regime for health professionals practising safely is unambiguous under the HPCA Act 2003. The Responsible Authority jurisdictions includes: determining the scopes of practice for the profession; prescribing the qualification for every scope of practice, ensuring that an applicant is fit and competent to practise within a scope of practice; reviewing a health practitioner's competence to practice; suspending a health practitioner's practising certificate; referring complaints against a health practitioner to the professional conduct committee or to the Health and Disability Commissioner for investigation or sanctions if necessary.

Checks and balances in HPCA Act 2003

51. Shifting the authorisation of prescribers into the detail to be included in a scope of practice published by Responsible Authorities requires establishing whether sufficient mechanisms for oversight are in place within the HPCA Act 2003. These are discussed in brief in the table below with some commentary as to whether changes would likely be required.

	Current requirements in HPCA Act 2003	**Possible changes required**
Scope of practice	Must be published by Gazette notice and qualifications must also be prescribed and published by Gazette notice. Currently it is not necessary for a scope of practice to specifically refer to a particular activity such as prescribing, only that the scope clearly countenances it.	If a scope of practice is to authorise prescribing activity then sufficient detail would need to be included in the scope of practice. We need to establish whether there is sufficient clarity and stringency in the way scopes of practice are currently published (although most appear to contain sufficient detail, it is possible that extra guidance may be required).

Consultation requirements	Section 14 states that before publishing a scope of practice, or before prescribing the qualifications required for a scope of practice, the Responsible Authority must have consulted: • with persons who the authority considers are able to represent the views of health practitioners, or of classes of health practitioner, registered with the authority; and • with organisations— (i) that the authority considers will be affected by the proposal; or (ii) whose members the authority considers will be affected by the proposal.	It appears that the consultation requirements as they currently stand in the HPCA Act are sufficient.
Approval of a new scope of practice or approval of a significant change to a scope of practice	In the HPCA Act there are no provisions for the Minister of Health to approve a scope of practice. Under the current medicines legislation the Minister of Health approves new or changed prescribing authority because legislation requires updating, or regulations drafted.	It might be necessary to include provisions for the approval of a scope of practice, or approval of a significant change to a scope of practice (ie, could be approved by the Minister or the Director-General of Health). As a sector we would need to agree criteria for what constitutes a significant change to a scope of practice.

Resolution of disputes	Section 127 outlines the resolution of disputes between two or more RAs following publication of a scope of practice. Each authority that is a party to the dispute must— • use its best endeavours to resolve the dispute; and • inform the Minister in writing of the nature and circumstances of the dispute; and • for every month that the dispute continues, provide the Minister with a written report on the progress being made to resolve the dispute. Under Section 128 the Minister retains considerable powers to require Responsible Authorities to resolve a dispute. Ie, Responsible Authorities must do or omit anything the Minister states, must cooperate with and implement the recommendations of a panel of experts appointed by the Minister and the directive is to be published by Gazette notice.	The current mechanisms for resolving disputes concerning scopes of practice in the HPCA Act will need review. What is not covered under current provisions are mechanisms for resolving disputes that arise: • before publication of a scope of practice • from any recognised body (not just between Responsible Authorities), ie, disputes may arise from professional bodies or colleges, or from within a group of registered practitioners.

Provisions to prevent an individual from prescribing	A health practitioner who acts outside his or her scope of practice is subject to oversight by his or her Responsible Authority. A Responsible Authority may suspend or cancel an Annual Practising Certificate or registration, or place conditions on an APC. They may take significant disciplinary action via a professional conduct committee or referral to the HPDT).	There appear to be sufficient mechanisms under the HPCA Act to prevent an individual from prescribing as required. However, feedback from the Responsible Authorities on this element is sought. Note, that under Section 48 of the Medicines Act 1981 the Minister has the power to prevent an individual from prescribing by issuing a prohibition notice. There has been some feedback that prohibition notices are not particularly effective.
Parliamentary oversight of a scope of practice	Under Section 14(4) a scope of practice is a disallowable instrument. This means it is subject to Parliamentary oversight and review by the Regulations Review Committee (and through these processes can be overturned).	No change proposed.

Accountability, enforcement and information sharing

52. The intention is that the rules and conditions by which the public can access prescription only medicines will be contained in the Therapeutic Products Bill. Appropriate offences and penalties will be tested as part of the exposure draft[5].

[5] The HPCA Act 2003 allows for specified activities to be restricted to registered health practitioners, in order to protect members of the public from the risk of serious or permanent harm. The provision for 'restricted activities' - a form of licensing - was included in the HPCA Act to provide an additional assurance that non-health practitioners would not be able to perform tasks that can only safely be performed by competent and registered health practitioners. It could be possible that prescribing become a restricted activity under Section 9 of the HPCA Act 2003, however, at this early stage the implications of this are not fully considered and will be subject to legal opinion.

53. An important part of any transition to a new regulatory regime is establishing a shared understanding between parties as relates to accountability. This also requires considering what needs to be notified and to whom, including any information sharing obligations to support regulatory functions (within established legal frameworks and protocols such as The Privacy Act and Health Information Privacy Code).

Questions for consideration:

- Do you support the proposal to shift the authorisation of prescribers into the detail of the scopes of practice for registered health practitioners (published by Responsible Authorities)? What are the advantages or disadvantages of this approach?
- Do you consider the consultation requirements to be adequate in the HPCA Act 2003 (refer Section 14 or table above)? Outline what, if anything, needs to change?
- What disputes have arisen with respect to scopes of practice in the past? Do further mechanisms for the resolution of disputes need to be considered? What should they entail (eg, use of an appointed panel)? (Refer Section 127 and 128 of the HPCA Act 2003.)
- Are the provisions in the HPCA Act 2003 to prevent an individual from prescribing (when deemed necessary) sufficient?
- Who needs to be able to share information with respect to prescribing or dispensing activity of concern? Are the protocols and accountabilities with respect to sharing information well understood? What needs to be improved, clarified or widened?

DELEGATED PRESCRIBERS

54. The delegated prescriber was introduced as a new prescribing category under the Medicines Amendment Act 2013. This category enables registered health professionals to prescribe within limited parameters (to be set out in a delegated prescribing order) under the sanction of an authorised (but not a designated) prescriber. The delegated prescribing order would set specific conditions and restrictions on prescribing (such as only certain medicines for certain patients) for an individual delegated prescriber. The competence, training and qualifications required of delegated prescribers would be set in consultation with the relevant responsible authority.

55. To date there has been no uptake of delegated prescribing, although some practitioner groups have indicated their interest. The following issues have been raised:

- delegated prescribing is perceived to hinder the legitimate progress of certain practitioner groups to prescribe on an independent basis
- the Ministry of Health has failed to provide adequate direction and support
- Standing Orders have been widely adapted over time and in many settings and therefore may have reduced the need for delegated prescribing
- establishing the training requirements for delegated prescribing and a lack of access to appropriate supervision to support delegated prescribing have acted as barriers to its uptake
- concerns remain regarding vicarious liability.

56. Similar, delegated prescribing arrangements exist in other jurisdictions. In the UK supplementary prescribing is a voluntary partnership between the responsible independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan (CMP) with the patient's agreement.

57. The parameters for what must be included in a clinical management plan are set out in regulations and include the illnesses or conditions which may be treated by the supplementary prescriber, the review date, medicines which may be prescribed or administered under the plan including any restrictions or limitations as to the strength or dose, adverse reactions and known sensitivities and the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan.

58. In the UK supplementary prescribing was introduced in 2003 for suitably trained nurses and pharmacists (and in 2006 nurses and pharmacists were enabled to independently prescribe almost all medicines within their clinical competence). In 2005, allied healthcare professionals such as physiotherapists, radiographers, podiatrists, and optometrists were also able to become supplementary prescribers.

Questions for consideration:

- Should a delegated prescriber category be retained in the new regulatory regime?
- Are there current or future service gaps or models of care that would lend themselves to delegated prescribing? Would amendments need to be made to the current delegated prescribing arrangements?

- If scopes of practice are used to authorise prescribing in the new regulatory arrangements, then a scope of practice could also identify who could prescribe on a delegated basis (and who could authorise a delegated prescribing order), including the training and competence requirements for doing so. What do you think of this option?
- Are there alternate prescribing arrangements to the delegated prescribing model that would better suited? For example, the use of clinical management plans such as in the UK that require patient agreement (refer paragraph 56).

STANDING ORDERS

59. A Standing Order is a written instruction issued by a medical practitioner or dentist[6]. It authorises a specified person or class of people (eg, paramedics) who do not have prescribing rights to administer and/or supply specified medicines (including some controlled drugs). The intention is for Standing Orders to be used to improve patients' timely access to medicines; for example, by authorising a paramedic in an emergency or a registered nurse in a primary health care setting.

60. A Standing Order does not allow a person to generate a prescription and provide it to a patient to take to a pharmacy to be dispensed (with the prescription signed later by the issuer of the Standing Order). Nor does a Standing Order allow a person to provide a patient with a prescription that has been 'pre-signed' by the medical practitioner or dentist who issued the Standing Order. Medicines and controlled drugs to be administered and/or supplied must be available on-site. The current regulatory detail is contained in Medicines (Standing Order) Regulations 2002, supported by Ministry of Health guidelines (http://www.health.govt.nz/publication/standing-order-guidelines).

61. In some settings the use of Standing Orders is considered safe and few concerns are expressed. This appears to be due to the presence of highly specialised staff and well-established protocols wrapped around the use of Standing Orders. Some concerns have been expressed about the use of Standing Orders in general practice and within some ambulance services. Concerns include the lack of regular auditing of Standing Orders and difficulties in determining competence to comply with a Standing Order.

62. Under the new regulatory regime, legislation will enable a Standing Order to be issued, with the detail, parameters and obligations of use to be included in a subordinate instrument (as is currently the case). The details to be developed throughout 2016 will include reviewing:

[6] Note that consultation is currently underway concerning Nurse Practitioner authority to issue Standing Orders.

- who is permitted to authorise a Standing Order and any obligations
- who is permitted to supply and administer under a Standing Order and any obligations
- the information a Standing Order must contain
- review periods, including reviews of competency
- auditing or monitoring requirements
- additional supporting guidance for sector.

63. To ensure Standing Orders are fit for purpose it is proposed a sector working group be established in mid-2016 to review their current use and provide advice concerning improvements to the way Standing Orders work.

64. As part of this work we will ask the working group to consider the interface between Standing Orders and independent and/or delegated prescribing as well as repeat prescribing (ie, the period of supply rules). The key aim will be to ensure high quality and convenient patient care, as well as the best use of the workforce, with particular respect to:

- timely and effective access to services in hard to service areas, and
- the best management of stable patients in primary care.

Questions for consideration:

- How might Standing Orders work better in the future? What needs to change?
- Please outline in detail any particular concerns you have with the current use of Standing Orders and consider possible solutions.

DISPENSING

65. Under the current arrangements, dispensing is defined in the primary statute (refer paragraph 18). Section 105 of the Medicines Act 1981 enables regulations to be made concerning the dispensing and compounding of medicines.

66. A similar approach is proposed for the new regulatory regime with an appropriate definition included in the primary statute and subsequent provisions to establish a legislative instrument (ie, regulations) to govern the rules and conditions of dispensing prescription therapeutic products.

67. Section 42 of the Medicines Regulations 1984 establishes that only an authorised prescriber, veterinarian, or pharmacist may dispense a prescription medicine. Additionally pharmacy

graduates, pharmacy technicians, dispensary technicians and students can dispense prescription medicines under the direct personal supervision of a pharmacist. At this stage no specific changes to these provisions are envisaged.

68. As noted earlier, definitions will be tested as part of the exposure draft of the Therapeutic Products Bill and the development of the regulatory detail concerning the rules and conditions of dispensing will be ongoing through 2016.

69. Note that the licensing regime for pharmacies will be consulted on separately.

Question for consideration:

- Are there particular issues you have with the parameters for regulating dispensing as noted in paragraphs 65 to 67?

DEVELOPMENTS TO SUPPORT THE REGULATORY FRAMEWORK

70. Discussions to date with stakeholders indicate that there are certain key developments that would usefully support a regulatory regime as relates to prescribing and dispensing. These include:

- the need for more robust prescribing and dispensing data (at the moment there are considerable errors in prescribing data and the Health Practitioner Index is not currently applied to all health practitioners nor reliably recorded)
- an IT enabled (eg, embedded in practice management systems) register of all registered health practitioners that would include scope of practice and prescribing authority information
- a single competency framework for prescribers independent of professional background to inform educational curricula and accreditation (note this is an action in the current action plan for the Medicines Strategy - Implementing Medicines New Zealand 2015 to 2020).

Question for consideration:

- Are there other key non-regulatory developments you consider important to support a new therapeutic products regulatory regime?
- Please raise any further aspects as you see fit.

APPENDIX 1: CONSOLIDATED QUESTIONS

- Are there other issues with the current regulatory arrangements that establish authorised and designated prescribers?
- Do you have any comments concerning the principles that govern the authorisation of prescribing in paragraph 44?
- Given the example outline above, are there further details needed in a scope of practice to authorise prescribing or to authorise the ability to issue a Standing Order?
- Do you support the proposal to shift the authorisation of prescribers into the detail of the scopes of practice for registered health practitioners (published by Responsible Authorities)? What are the advantages or disadvantages of this approach?
- Do you consider the consultation requirements to be adequate in the HPCA Act 2003 (refer Section 14 or table above)? Outline what, if anything, needs to change?
- What disputes have arisen with respect to scopes of practice in the past? Do further mechanisms for the resolution of disputes need to be considered? What should they entail (eg, use of an appointed panel)? (Refer Section 127 and 128 of the HPCA Act 2003.)
- Are the provisions in the HPCA Act 2003 to prevent an individual from prescribing (when deemed necessary) sufficient?
- Who needs to be able to share information with respect to prescribing or dispensing activity of concern? Are the protocols and accountabilities with respect to sharing information well understood? What needs to be improved, clarified or widened?
- Should a delegated prescriber category be retained in the new regulatory regime?
- Are there current or future service gaps or models of care that would lend themselves to delegated prescribing? Would amendments need to be made to the current delegated prescribing arrangements?
- If scopes of practice are used to authorise prescribing in the new regulatory arrangements, then a scope of practice could also identify who could prescribe on a delegated basis (and who could authorise a delegated prescribing order), including the training and competence requirements for doing so. What do you think of this option?
- Are there alternate prescribing arrangements to the delegated prescribing model that would better suited? For example, the use of clinical management plans such as in the UK that require patient agreement (refer paragraph 56).
- How might Standing Orders work better in the future? What needs to change?

- Please outline in detail any particular concerns you have with the current use of Standing Orders and consider possible solutions.
- Are there particular issues you have with the parameters for regulating dispensing as noted in paragraphs 65 to 67?
- Are there other key non-regulatory developments you consider important to support a new therapeutic products regulatory regime?
- Please raise any further aspects as you see fit.