Consultation on Principles for quality and safe prescribing practice

29 June 2023

Submission closing date: 31 August 2023

Dental Council
Te Kaunihera Tiaki Niho

Te Kaunihera Rata o Aotearoa
Medical Council of New Zealand

Te Kaunihera Tapuhi o Aotearoa
Nursing Council of New Zealand

Dietitians Board
Te Mana Mātanga Mātai Kai

Te Tatau o te Whare Kahu
Midwifery Council

pharmacycouncil
Te Pou Whakamana Kaimatū o Aotearoa

Optometrists and Dispensing Opticians Board
Te Poari o ngā Kaimātai Whatu me ngā Kaiwahakarato Mōhiti

Contents

Purpose

1. The following responsible authorities are seeking feedback on the statement on *"Principles for quality and safe prescribing practice"* (see Appendix 1):

    a. Dental Council of New Zealand | Te Kaunihera Tiaki Niho o Aotearoa

    b. Dietitians Board of New Zealand | Te Mana Mātanga Mātai Kai

    c. Medical Council of New Zealand | Te Kaunihera Rata o Aotearoa

    d. Midwifery Council | Te Tatau o te Whare Kahu

    e. Nursing Council of New Zealand | Te Kaunihera Tapuhi o Aotearoa

    f. Optometrists and Dispensing Opticians Board of New Zealand | Te Poari o ngā Kaimātai Whatu me ngā Kaiwahakarato Mōhiti

    g. Pharmacy Council of New Zealand | Te Pou Whakamana Kaimatū o Aotearoa

Context and rationale for development

2. The purpose of the Health Practitioners Competence Assurance Act 2003 is to protect the health and safety of the public by providing mechanisms to ensure that health practitioners are competent and fit to practise their profession.[1]

3. The responsible authorities have powers, duties, and functions under the Health Practitioners Competence Assurance Act 2003.

4. There are currently 18 responsible authorities mandated under the Health Practitioners Competence Assurance Act 2003.[2]

5. Of those, seven responsible authorities regulate health practitioners who are authorised to prescribe (see paragraph 1). These responsible authorities seek to develop a *"Principles for quality and safe prescribing practice"* statement.

    a. Currently, the health practitioner groups that have prescribing authority in Aotearoa New Zealand include dentists, dietitians, medical practitioners, midwives, nurses, nurse practitioners, optometrists, and pharmacist prescribers.

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[1] Health Practitioner Competence Assurance Act (HPCAA) 2003, section 3.
[2] Ministry of Health – Manatū Hauora. (2023, Feb 9). Responsible authorities under the act. Retrieved June 13, 2023, from https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act

6. This work falls within the functions of the responsible authorities as mandated by the Health Practitioners Competence Assurance Act 2003. Specific functions that are relevant include to:
    a. “set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession”,
    b. “ liaise with other authorities appointed under this Act about matters of common interest”, and
    c. “ promote and facilitate inter-disciplinary collaboration and co-operation in the delivery of health services”.[3]

7. There is evidence that current prescribing practice provides suboptimal outcomes via equitable access to services, and over-, under-, and misuse of therapeutic products.[4,5,6,7,8] This contributes to avoidable morbidity, mortality, demand for health services, and waste.

8. The primary rationales for developing this statement include:
    a. improving the quality of prescribing (and therefore contributing to improved health outcomes) by expecting that all prescribers practise according to the principles that the statement outlines, and
    b. mitigating risk to the public by ensuring consistent regulation for prescribers (with respect to the prescribing activity) irrespective of professional background.

9. As the prescribing workforce becomes more diverse, with respect to professional background of practitioners, it is increasingly important that expectations for prescribing are robust and consistent.

10. Secondary benefits to a collaborative statement include:

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[3] Health Practitioner Competence Assurance Act 2003, section 118 see functions (i), (j), and (ja).
[4] The Health & Disability Commissioner (2018). Complaints Closed by the Health and Disability Commissioner about Medication Errors: Analysis and Report 2009–2016. Auckland, NZ.
[5] Avery, T., et al. (2012). Investigating the prevalence and causes of prescribing errors in general practice: The PRACtICe Study (PRevalence And Causes of prescrIbing errors in general practiCe), General Medical Council.
[6] Nichols, Pamela, Tandy-Sue Copeland, Ian A. Craib, Paul Hopkins, and David G. Bruce. "Learning from error: identifying contributory causes of medication errors in an Australian hospital." Medical Journal of Australia 188, no. 5 (2008), 276-279.
[7] Roughead, E. E. and S. J. Semple (2009). "Medication safety in acute care in Australia: where are we now? Part 1: a review of the extent and causes of medication problems 2002-2008." Australia & New Zealand Health Policy 6: 18.
[8] Council of Europe Expert Group on Safe Medication Practices (2006). "Creation of a better medication safety culture in Europe: building up safe medication practices." Retrieved 22/12/2022, from http://optimiz-sih-circ-med.fr/Documents/Council_of_Europe_Medication_Safety_Report_19-03-2007.pdf.

a. improved interdisciplinary understanding of the competencies and role of other prescribing health professions,
b. reduced barriers to interdisciplinary collaboration, and
c. harmonisation with international regulatory models.

11. As existing prescribing competence standards become due for review or additional health professions gain prescribing authority, the statement may be used as a framework by responsible authorities to provide even greater regulatory consistency with respect to prescribing.

12. Healthcare and societal expectations regarding equitable access, cultural safety, and giving effect to Te Tiriti o Waitangi have strengthened recently. As such, this statement also takes the opportunity to communicate contemporary expectations regarding culturally safe practice and giving effect to Te Tiriti o Waitangi when prescribing.

13. While the statement has been developed collaboratively by the responsible authorities and will be adopted jointly, each responsible authority may contextualise and operationalise the document with specific reference to its own work programme.

14. This statement is not positioned as a competence framework or as competence standards. This statement communicates broad principles while specific required competencies are found within the competence standards of the relevant responsible authority (dependant on professional background of the prescriber).

15. Factors that lead to suboptimal prescribing are complex and multiple. Many of these factors are outside the direct control of individual prescribers and outside of the mandate of the responsible authorities. This statement describes expected individual practices which are likely within the control of the prescriber and related to their competence to fitness to practise their profession.

16. We anticipate that the main audience for the statement will be practitioners who prescribe or plan to prescribe. However, the statement will also inform policymakers and members of the public of agreed joint standards when accessing prescribed therapeutic products.

17. The statement is based on the regulatory model primarily described by Medicines Act 1981 and Misuse of Drugs Act 1975.

18. While we are aware of the possible impact of the Therapeutic Products Bill, the changes from its enactment will not be operationalised for a few years.

19. The responsible authorities have developed this statement, focusing on current context of practice, and agreed approach across responsible authorities.

20. The responsible authorities consider the statement's principled approach is unlikely to be impacted by the Therapeutic Products Act. However, we recognise the need for annual (or more frequent) review, to ensure it remains current, and representative of the joint view of the responsible authorities. Definitions may require update as Medicines Act 1981 and Medicines Regulations 1984 are repealed.

Development Process

21. Work on this project commenced in 2020 during an environmental scan by Pharmacy Council of New Zealand of prescribing competence frameworks and standards in international jurisdictions.

22. This preparatory work was being undertaken by Pharmacy Council for update of the competence standards for pharmacist prescribers.

23. The scan identified regulatory models in the United Kingdom and Australia where prescribing frameworks had been adopted across multiple health professions.[9,10]

24. This interprofessional model proved to be of value in these jurisdictions by "supporting quality prescribing decisions by all prescribers".[10]

25. The (then) Director-General of Health, Dr Ashley Bloomfield, was briefed on the proposed approach for a joint prescribing framework and he supported it (see Appendix 2).

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[9] Royal Pharmaceutical Society. A competency framework for all prescribers. London, 2021.
[10] NPS MedicineWise. Prescribing Competencies Framework: embedding quality use of medicines into practice (2nd Edition). Sydney, 2021

26. The responsible authorities explored the potential for a single set of competence standards that could be adopted across the professions. This option was determined to be difficult to implement due to different regulatory models and mixes.

27. An agreed feasible option identified was the development of a joint responsible authority statement which outlines the expectation of safe and high-quality prescribing for prescribing health practitioners regardless of professional background.

28. This statement would be written generically at a principle- level applicable to all prescribers and supplemented by further regulatory tools from each responsible authority as applicable and necessary for their profession.

29. The statement has been strongly influenced by the overseas competence frameworks and Medical Council of New Zealand's statement on good prescribing practice.[9,10,11]

30. The development of the document presented for consultation is the product of a collaborative process by, and feedback from, the responsible authorities.

[11] Medical Council of New Zealand - Te Kaunihera Rata o Aotearoa. Statement on good prescribing practice. Wellington, 2020.

Feedback and submission process

31. The responsible authorities are seeking the following feedback from all stakeholders:

a. Do you consider that it is valuable to have a statement for *Principles for quality and safe prescribing practice* applying across all prescribers?

b. Are the principles set at a reasonable and fair level which protects the health and safety of the public? (Bear in mind that the statement supplements each responsible authority's standards, statements, and guidance).

Optional questions:

c. Do you agree with the introduction sections of the statement, (i.e., the Purpose, Definitions, and Background sections)?

d. Do you agree with **Principle 1: Assess the person**?

e. Do you agree with **Principle 2: Consider the options**?

f. Do you agree with **Principle 3: Present options and come to a shared decision**?

g. Do you agree with **Principle 4: Prescribe**?

h. Do you agree with **Principle 5: Inform**?

i. Do you agree with **Principle 6: Monitor effectiveness and safety of treatment and review options**?

j. Do you agree with **Principle 7: Practise equitably**?

k. Do you agree with **Principle 8: Prescribe safely**?

l. Do you agree with **Principle 9: Ensure adequate record keeping**?

m. Do you agree with **Principle 10: Prescribe professionally**?

n. Do you agree with **Principle 11: Encourage quality improvement**?

o. Do you agree with **Principle 12: Collaborate**?

p. Do you have any additional comments?

Please click here to start your submission. Thank you!

Appendix 1: Principles for quality and safe prescribing practice

Principles for quality and safe prescribing practice

Purpose

1. This document aims to assist health practitioners who prescribe (prescribers) to undertake and maintain quality prescribing practice by identifying a common set of principles that apply when prescribing therapeutic products.

2. Quality prescribing will ultimately contribute to improved and more equitable health outcomes for people when therapeutic products are considered as a treatment option.

Definitions

3. For the purposes of this document, the following definitions are adopted.

   a. **Equity:** the absence of unfair, avoidable, or remediable differences among groups of people. Equity acknowledges that not only are differences in health status unfair and unjust, but they are also the result of differential access to the resources necessary for people to lead healthy lives.[1,2]

   b. **Medicine:** any prescription medicine, restricted medicine, pharmacy-only medicine, or general sale medicine as determined by Medicines Act 1981 and Medicines Regulations 1984; and any controlled drug as determined by the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977.

   c. **Prescriber:** any authorised prescriber (including designated prescribers) or delegated prescriber as determined by the Medicines Act 1981.[3] At the time of publication, health practitioner groups that have prescribing rights in New Zealand include dentists, dietitians, medical practitioners, midwives, nurses, nurse practitioners, optometrists, and pharmacist prescribers.

   d. **Person** and **people** are used in this document in a general manner which may include but is not limited to, the public, the consumers of healthcare at both an individual or population level, and whānau – and so needs to be interpreted in accordance to the context and setting.

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[1] World Health Organisation. (2022). Health Equity. https://www.who.int/health-topics/health-equity#tab=tab_1

[2] Ministry of Health. (2022). Equity. https://www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga/key-threads/equity

[3] See Medicines Act 1981 s3 (definitions of 'authorised prescriber' and delegated prescriber).

e. **Prescribing:** an iterative process including information gathering, clinical decision making, communication, and monitoring and review use of therapeutic products.

f. **Therapeutic product:** any product intended to be used in or on human beings for a therapeutic purpose.[4] This includes medicines, related products, or medical devices. Where appropriate and applicable, this includes both approved and unapproved products.

g. **Whānau:** an extended family or a family group and is the primary economic unit of Māori society. In the modern context, whānau is sometimes also used to include friends who may not have kinship ties to other members.[5]

Background

4. Medication is the most common intervention in health care.[6] While therapeutic products provide great benefit, there is also evidence that inappropriate prescribing (over-, under-, and misuse of therapeutic products) is prevalent in Aotearoa New Zealand. This contributes to avoidable morbidity, mortality, demand for health services, and waste. This document sets out principles which outline an approach to quality prescribing.

5. While there are multiple potential contributors to inappropriate prescribing, many of which are outside the direct control of individual prescribers; this document communicates expected behaviours which are within the control of the prescriber.

6. It is expected that these principles will be applicable in the vast majority of cases, but prescribers must contextualise the principles to their specific circumstances.

7. The joint approach by the responsible authorities also aims to reduce unwarranted variation in prescribing by providing a consistent regulatory approach for all prescribers irrespective of professional background or practice setting.

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[4] Medsafe. Guideline on the regulation of therapeutic products in New Zealand. Wellington: Medsafe, 2014. overview-of-therapeutic-product-regulation.pdf.
[5] Moorfield, J. C. (2022). Whānau. Te Aka Māori Dictionary. https://maoridictionary.co.nz/search?idiom=&phrase=&proverb=&loan=&histLoanWords=&keywords=whanau
[6] The Health & Disability Commissioner (2018). Complaints Closed by the Health and Disability Commissioner about Medication Errors: Analysis and Report 2009–2016. Auckland, NZ.

8. Quality care is people-centred, equitable, accessible, safe, effective, and efficient.[7] With equity and accessibility being key dimensions of quality, health practitioners prescribing in Aotearoa New Zealand must also be committed to upholding and enacting Te Tiriti o Waitangi ngā mātāpono – principals, including the provision of culturally safe prescribing practice to people and whanau.

9. The principles are grouped within two categories. The 'person-centred prescribing process' includes sequential steps to guide individual prescribing interactions.

10. Initial diagnosis is not addressed by this document because not all prescribers act as a primary diagnostician. Please refer to standards and guidance from your responsible authority if primary diagnosis is part of your role.

11. The principles within 'professional practice to support quality and safe prescribing' relate to prescribing governance. These principles underpin and facilitate the 'person-centred prescribing process'. All the principles must be interpreted with reference to each other as they are complementary. They must also be read in conjunction with other standards and statements published by the relevant responsible authority.

12. This document may be used by responsible authorities, the Health Practitioners Disciplinary Tribunal, and the Health and Disability Commissioner as a standard by which quality and safe prescribing is measured. It may also be used by responsible authorities as a framework to guide national consistency when setting prescribing related competence standards and ethical behaviour.

7 Ministry of Health. 2003. Improving Quality (IQ): A systems approach for the New Zealand health and disability sector. Wellington: Ministry of Health.

Person-centred prescribing process

Principle 1: Assess the person

13. Prior to prescribing, a prescriber ensures that they have an appropriate understanding of a person's circumstances. This includes assessment of their medical[8] and medication history[9], social circumstances (including social networks), and healthcare values, beliefs, and goals. It may also include consideration of the expertise, role, and care of their whānau.

14. Both the person and clinical records are important sources of information to ensure as full an understanding as possible of the person's circumstances and needs.

15. To ensure the person can divulge all relevant information, a prescriber must provide a safe and non-judgemental environment.

16. Today, many clinical records are held within cloud-based clinical information sharing platforms. A prescriber must be able to use these platforms to access relevant information.

17. Consultation with the person is required if prescribing any therapeutic product for the first time.

18. Consultation may occur via telehealth if the prescriber can provide safe and quality healthcare, and the consumer consents to telehealth services.

19. A prescriber should evaluate a person's level of health literacy and communicate in a way that is best understood by the person and is culturally safe.[10]

Principle 2: Consider the options

20. A prescriber considers the range of evidence-informed treatment options that may benefit the person. This includes providing no treatment, non-pharmacological approaches and therapeutic products, medicines, and stopping or adjusting the dose of medicines that might be causing harm, or no longer be of benefit (deprescribing).

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[8] This includes family medical history and known drug allergies.

[9] This includes but is not limited to prescribed medicines, over-the-counter medicines, Rongoā, complementary and alternative therapies, vaccines, and recreational drugs.

[10] In the context of quality and safe prescribing practice, the concept of cultural safety used is consistent with that as articulated in Curtis et al; Why Cultural safety rather than cultural competence is required to achieve health equity: a literature review and recommended definition; International Journal for equity in Health (2019) 18: 174

21. When considering these options, the prescriber considers the current best available evidence as applicable to the individual person concerned, as well as the person's particular circumstances and preferences including their ability to take or use any therapeutic product and potential monitoring requirements.

Principle 3: Present options and come to a shared decision

22. A prescriber presents the treatment options to the person. This should include appropriate information about the expected risks, adverse effects, and benefits of each option.

23. This information should be presented in a way that people can understand and that minimises perceived and actual power imbalance to facilitate informed choice and a shared decision on a mutually agreed treatment plan.

Principle 4: Prescribe

24. A prescriber prescribes therapeutic products only when there is a clear clinical need or justification.

25. They ensure that the therapeutic product, dose, dose frequency, route of administration, and quantity/period of supply are appropriate and safe for the person.

26. A prescriber issues a prescription (either electronic, physical, or verbal) that meets all legal and professional requirements with unambiguous instructions for dispensing and administration according to the treatment plan.

27. A prescriber recognises that inappropriate prescribing (which may include indiscriminate, excessive, or reckless prescribing) is clinically and ethically unacceptable. It may be harmful to people and society[11] and undermines trust in the health professions and other health practitioners.

Principle 5: Inform

28. A prescriber ensures that the person understands the treatment plan (including what action to take if they have concerns), how to access and use the prescribed therapeutic products, and any monitoring requirements.

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[11] By the wasteful use of limited resources and contributing to problems such as antimicrobial resistance and diversion to the black market.

29. As far as possible, according to the person's capability and the health care context, a prescriber empowers people to take responsibility for their own health and self-manage their conditions by providing appropriate resources and advice.

Principle 6: Monitor effectiveness and safety of treatment and review options

30. A prescriber ensures there are appropriate follow up mechanisms in place to monitor the effectiveness and tolerability of treatment, and for the person to raise concerns and/or provide feedback as required.

31. When necessary, a prescriber reviews treatment options with the person seeking to optimise outcomes. Continuation or modification of treatment should be based on the assessment of progress towards the shared treatment plan and according to best practice.

Professional practice to support quality and safe prescribing

Principle 7: Practise equitably

32. A prescriber recognises that quality of care and health outcomes within Aotearoa New Zealand are inequitable.

33. They acknowledge and work to give effect to Te Tiriti o Waitangi by demonstrating an understanding of Māori Indigenous rights and issues in relation to health and health equity, and by engaging in culturally safe practice.

34. This includes self-reflection on how their own biases impact on their thinking and behaviour, minimising the power differential with people, committing to transformative change in their practice, and ensuring that people and whānau define what culturally safe care means to them. A prescriber recognises that cultural safety benefits all people and communities.

Principle 8: Prescribe safely

35. A prescriber prescribes therapeutic products that are within their legal authority, scope of practice, and that they are competent to prescribe safely.

36. A prescriber maintains a contemporary knowledge of therapeutic products within their area of clinical practice. This includes being familiar with the indications, adverse effects, contraindications, major drug interactions, appropriate dosages, monitoring requirements, effectiveness and cost-effectiveness of the therapeutic products prescribed.

37. A prescriber should consult resources as required, including peer-reviewed literature and up to date formularies and guidelines, to ensure safe prescribing practice.

Principle 9: Ensure adequate record keeping

38. A prescriber keeps clear, accurate and timely records of prescribing. This should document all information relevant to the prescribing and include details of any adverse drug reactions and information given to the person about the treatment prescribed.

Principle 10: Prescribe professionally

39. A prescriber maintains professional independence and ensures that prescribing decisions are based on the best available evidence to ensure safe and effective care.

40. This includes maintaining personal, professional, and financial boundaries to ensure that real or perceived conflicts of interest are effectively declared and managed.

41. A prescriber accepts personal responsibility and accountability for prescribing decisions and ensures that they can provide sound rationale for their decision.

Principle 11: Encourage quality improvement

42. A prescriber promotes and engages with the principles of clinical governance and safety culture to ensure continuous improvement of the care provided to people.

43. A prescriber ensures high-quality prescribing processes to minimise medication and/or prescribing errors, and inequitable practice.

44. They acknowledge prescribing errors when they occur and act accordingly to minimise harm.

45. A prescriber identifies areas of potential improvement by taking part in prescribing audits, peer review, self-reflection, and continuing education. They use both qualitative and quantitative self-reflection and external data and feedback to improve prescribing knowledge and practice.

46. Quality improvement extends across all aspects of prescribing including, but not limited to clinical decision making, professionalism, communication, and culturally safe and equitable practice.

Principle 12: Collaborate

47. A prescriber understands they are a member of a collaborative, multidisciplinary team responsible for providing holistic care to each person under their care.

48. With the person's permission, relevant information is appropriately shared with other providers of care to ensure effective transfer and continuity of care.

49. A prescriber both provides and seeks feedback and support from colleagues to optimise care.

Appendix 2: Letter from the Director-General of Health (dated: 15 September 2020)

133 Molesworth Street
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15 September 2020

HR20201310

Michael Pead
Chief Executive
Pharmacy Council of New Zealand
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Email: m.pead@pharmacycouncil.org.nz

Dear Michael

Single prescribing competency framework for all prescribers

Thank you for the opportunity to kōrero with you, your board and senior staff on 24 June 2020.

It was an enjoyable opportunity to engage on the role of Pharmacy Council in ensuring public safety and the potential future direction of Pharmacy Council's regulatory role to support its vision of being a future focussed enabling regulator.

In particular you raised a desire for Ministry endorsement to continue the collaborative work you have initiated across the Responsible Authorities to develop a single prescribing competency framework for all New Zealand prescribing health practitioners. I would like to confirm our support for your continued collaborative work to this end and wish you well with your endeavours.

Nāku noa, nā

Dr Ashley Broomfield
Director-General of Health