Therapeutic Products Consultation: Submitter Profile

If you elect not to use the online tool to complete your submission, please ensure you complete the following submitter profile form and send in via email with your submission.

☐ Individual ☒ Organisation

Name (of individual or organisation): Dental Council

Email address: consultations@dcnz.org.nz

Profile (tick all that apply)

Perspective

☒ Consumer ☐ Disabled person ☐ Māori ☐ Pacific peoples

☐ Other Click here to enter text.

Industry

☐ Industry body
☐ Advertising
☐ Retailer (non-pharmacy)

Importer
☐ Medical devices
☐ Medicines
☐ Cells and tissues
☐ Active ingredients
☐ Veterinary medicines

Manufacturer
☐ Medical devices
☐ Medicines
☐ Cells and tissues
☐ Active ingredients
☐ Veterinary medicines

Wholesaler
☐ Medical devices
☐ Medicines

Health sector

☐ Professional body (eg, Colleges, Pharmaceutical Society etc)
☐ Health service provider (eg, Ambulance, Māori or Pacific health provider etc)
☐ Private hospital
☐ Pharmacy organisation
☐ District Health Board (DHB) - please state which service area: Click here to enter text.

Health practitioner

☐ Pharmacist
☐ Nurse
☐ Midwife
☐ Dentist
☐ Surgeon
☐ Optometrist
☐ Dietician
☐ Medical practitioner (excluding Surgeons)

☐ Other health practitioner (please comment) Click here to enter text.

Clinical trials

☐ Medicines (other than cell and tissue)
☐ Medical devices
☐ Cells and tissues
☐ Trial ethics

Other
☐ Government agency
☐ Crown entity
☐ NGOs
☐ Veterinarian
☒ Other (please comment) Health regulator

Official Information Act statement

Your submission may be requested under the Official Information Act 1982. If this happens, the Ministry will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

Submission response

Introduction

1. The Dental Council (the Council) is the regulatory authority tasked under the Health Practitioners Competence Assurance Act 2003 (the HPCAA) to regulate oral health practitioners in New Zealand. The Council's functions are set out in s118 of the HPCAA.

2. The Council regulates approximately 4800 oral health practitioners. This includes dentists, dental specialists, oral health therapists, dental hygienists, dental therapists, clinical dental technicians, dental technicians and orthodontic auxiliaries.

3. Thank you for the opportunity to provide feedback on the draft legislation.

4. The Council welcomes the update to the Therapeutics Products Bill (the Bill) to protect patient safety and contribute towards keeping New Zealand society healthy and productive.

5. We support the Bill's contemporary and future-looking approach. In particular, we consider the Bill's new structure will mean sub-ordinate legislation can be updated more quickly and efficiently.

6. Our submission focusses on areas of the Bill that we consider impact on oral health practitioners' practice most directly.

7. Many of our comments seek to clarify and eliminate any possible uncertainty or ambiguity on aspects of the Bill. Our comments may also inform the more detailed sub-ordinate legislation that will be drafted to support the Therapeutics Products Regulatory Scheme and the Therapeutics Products Act when enacted.

8. Our submission follows the same structure as the consultation questions although we have limited our responses to Council-relevant questions at this stage.

9. Please contact us if you have any questions about our submission. We would welcome the opportunity to further discuss and better understand the intended regulatory provisions for dental appliances with Ministry staff.

10. In particular, we are keen to be involved with the development of draft regulations or rules that impact on oral health practice.

Response to consultation questions

Chapter A

A1. Do you support the general design of the new regulatory scheme for therapeutic products?

1 Support

2 Partially support ☒

3 Neutral

4 Partially don't support

5 Don't support.

11. The Council supports most of the new proposed regulatory scheme design.

12. Our primary concerns relate to the following areas:

i. Scope of therapeutics products included

13. Our concern is about the scope and volume of medical devices that could potentially be incorporated into the regulatory environment for the first time.

14. In the absence of the supporting regulations or other regulatory tools to provide greater insight into the products that will be included under the definition of medical devices and the risk-proportionate approach that will be used, our concerns at this point are:

- the broad definition of medical devices, and as a result, the potentially large number of medical devices that could be captured in the new regulatory scheme that have never been regulated in New Zealand before
- the capacity and available expertise on medical device regulation required across diverse and often specialised areas
- potential down-stream price increases to cover additional regulatory compliance costs that could impact affordability for patients
- risk of disrupting the supply of medical devices.

15. The Council believes that the factors listed above could compromise access to these medical devices, which in turn could adversely impact care to New Zealanders.

16. The Council strongly encourages a pragmatic and staggered approach using a robust risk framework to clearly identify and prioritise those medical devices that require immediate regulatory intervention. The scope of therapeutic products to be regulated can be subsequently broadened using the same risk framework as a reference.

ii. Uncertainty about the regulatory framework proposed for oral health practitioners prescribing, using, supplying, designing, manufacturing, repairing and importing dental appliances – both fixed and removable appliances

17. The Bill makes several possible pathways available to regulate dental appliances. We are concerned about the potential impact of these new requirements on patients and oral health practitioners. Our understanding of these various regulatory pathways and the potential obligations on practitioners are detailed later in our submission.

18. We would like to discuss the proposed legal and regulatory framework further with Ministry staff to better understand the potential obligations for dental appliances.

19. The Council has no evidence of systemic risk to patient safety or harm resulting from the use of dental appliances under the current regulatory framework, where the health practitioner is subject to regulation, rather than the devices they produce.

20. The Council relies on the practitioner's ethical and professional obligations to ensure patients receive the appropriate quality of treatment and to ensure patient safety is central to the practitioner's treatment plan.

21. As noted for other medical devices, the Council encourages a pragmatic, risk-based approach to the regulation of dental appliances.

iii. Potential regulatory overlap relating to the professional competence and conduct of registered oral health practitioners

22. The Council is responsible under the HPCAA to assure oral health practitioners meet the ethical, cultural and clinical competence standards we set. If the Council is satisfied each year that a practitioner meets these standards, the Council issues a practising certificate. The Council is responsible for managing practitioners who fall short of our standards by putting mechanisms in place to ensure they meet the minimum standards required.

23. The Bill empowers a Regulator to control the manufacture, distribution, supply, prescribing and dispensing of medicines, medical devices, active medicinal ingredients and a fourth unknown category.

24. Our view is that extending the regulatory powers and functions of the Regulator as set out in the Bill could lead to potential areas of regulatory overlap, duplication of effort, or grey areas that possibly create unintended gaps.

25. The risks set out in paragraph 24 above relate particularly to monitoring and managing issues of professional competence and conduct of health practitioners when they supply, prescribe, dispense, distribute or manufacture therapeutic products.

26. We believe that the competence and conduct of health practitioners, and the clinical, professional and ethical standards they must meet correctly fall under the remit of health regulators.

27. In our view, the Regulator for the Therapeutics Products Regulatory Scheme should focus on the manufacturing and delivery of therapeutic products, including the licensing of associated facilities. The health regulators can then focus on the activities and standards related to clinical decision-making such as prescribing, supplying, dispensing and administration of the therapeutic products.

28. We believe clearly differentiating regulatory powers is essential to protecting public safety and avoiding regulatory overlap or gaps. We welcome further discussion with the Ministry and the other health regulators to explore ways to achieve this.

iv. Potential discrepancy in professional and licencing obligations between pharmacists and other health practitioners supplying and dispensing medicine within their scopes of practice

29. The Bill proposes expanding the supply of medicine by health practitioner prescribers, within their scope of practice. Based on our reading, we do not believe there is a requirement for the premises where health practitioners supply medicines to have a pharmacy licence and meet similar licensing obligations.

30. The Bill further allows for staff of health practitioner prescribers to supply category 3 medicines to patients, subject to the health practitioner's scope of practice and under general supervision (not defined). We do not consider non-trained and non-registered staff should supply or dispense category 3 medicines to patients.

31. Although we support increasing access to medicines, the Council believes the same professional and ethical standards across all health practitioners who supply and dispense medicines should be applied.

Chapter B

Part 1: Preliminary provisions

B1 Please provide any comments on the purpose or principles of the Bill (ss 3 and 4)

33. The Council supports the need for robust and effective quality assurance for therapeutic products used on patients in New Zealand. We also support the guiding principles expressed in the Bill and the risk-proportional approach to regulation.

34. We propose that the principles also include recognising the importance of ethical and professional behaviour to ensure patient safety is protected.

Part 1: Interpretation

B2 Please provide any comments on the definitions or meaning set out in the draft Bill (ss 14-50)

35. We suggest the definitions for prescribers, registered health practitioners and scopes of practice in the HPCAA and the Bill should be consistent. This may require amending HPCAA definitions to align with definitions in the Bill.

Part 3: Dealing with therapeutic products

The following section includes commentary related to the following consultation questions:

B3 Please provide any comments on the product approval controls (ss 51 and 52)

B4 Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55)

B7 Please provide any comments on the authorisations for health practitioners (ss 61-64)

B8 Please provide any comments on the authorisations for health practitioners' staff (s 65)

B11 Please provide any comments on the authorisations created in sections 71–75 and sections 78–80

B12 Please provide any comments on the offences created in sections 81–94

36. Our questions or areas of concern relate to the following areas:

v. Uncertainty about the regulatory framework proposed for oral health practitioners prescribing, using, supplying, designing, manufacturing, repairing and importing dental appliances – both fixed and removable appliances

Context

37. We are unclear about product approval requirements and regulatory obligations for oral health practitioners as they relate to dental appliances.

38. Regulation in this space could involve more than half our registered oral health practitioners (approximately 3,200 practitioners). Dentists, dental specialists, clinical dental technicians and

dental technicians' scopes of practice allow for various clinical activities related to dental appliances.

39. Examples of activities relating to dental appliances that oral health practitioners are involved in include:

    - A dentist or dental specialist prescribes a dental appliance for a patient. A dental technician or clinical dental technician then design and manufacture the appliance and initially fit it. The dentist or dental specialist does the final fit or implant.

      The dentist or dental specialist can also manufacture the dental appliance.

    - Dental technicians and clinical dental technicians can manufacture some appliances without a prescription. The patient needs an oral health certificate from a dentist to ensure the patient mouth is healthy before making and fitting the appliance.
    - Some already manufactured appliances, or components of such appliances are used by oral health practitioners on patients. For example, orthodontic braces and related components.
    - Some appliances are directly sought by patients and then designed, modified and sold to patients – such as mouth guards for bruxism (teeth grinding) or sports and snoring appliances.
    - Appliances can be repaired or adjusted by dental technicians, clinical dental technicians, dentists or dental specialists.

40. Dental appliances cover a range of products such as dental implants, orthodontic appliances, crowns and bridges, dentures, overdentures and many more. These appliances can be either fixed or removable, and used for short periods or be permanent.

41. Dental appliances can often be prescribed or designed by an oral health practitioner in New Zealand but manufactured overseas. The final fitting and clinical responsibility of the dental treatment remains with the New Zealand registered oral health practitioner.

42. Some patients order their own dental appliances online, mostly from overseas companies.

43. Manufacturing facilities of dental devices are diverse, ranging from small spaces in a private dental practice, to dental laboratories, hospitals and educational laboratories, international laboratories or well-established international companies.

44. The consultation document states that "*The Bill would provide health practitioners with the authorisations required for the activities that they currently perform under the Medicines Act 1981*" [para 549].

45. We interpret this as health practitioners being able to continue to perform the same activities under the new therapeutic products regulatory scheme as before.

46. To ensure that this remain the case for oral health practitioners, we need clarification on the regulatory pathways and obligations associated with dental appliances. We want to ensure that the new obligations are not placing unreasonable requirements deterring practitioners to continue to manufacture high quality dental appliances – that could limit availability and patient access to dental appliances.

Our interpretation of the Bill's regulatory obligations related to dental appliances as medical devices

47. The Council considers that most dental appliances fall under the definition of:

- therapeutic products [s16(1)(a)] by achieving one or more of the therapeutic purposes defined under s15(1). In particular sub-sections:
  - *(f)...replacing, modifying or supporting part of a human's anatomy*
  - (a) *preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury;* and
- a medical device under s21(1)(a)(i).

48. All therapeutic products covered under the Bill will have an approval status described under s24, being:

- approved
- approval-exempt
- unapproved product.

49. Section 51 prevents a person from importing or supplying a therapeutic product unless:

- it is an approved or approval-exempted product, or
- a person is authorised by a licence, permit or provision under subpart 3 of Part 3.

50. Certain activities, defined as controlled activities in s53(2), are prohibited unless the person wishing to undertake those activities has a permit, or a licence, or is authorised to do so under the Bill.

51. Controlled activities relating to medical devices include:

- manufacturing
- wholesale supply
- non-wholesale supply
- use of supply-restricted devices contrary to the regulations.

52. Activities not defined as controlled activities can be freely undertaken or are subject to the regulations or rules that will ultimately be passed under the Bill. Some of these activities are only able to be carried by certain types of persons (e.g. health practitioners); others can be done by any person.

53. Based on our interpretation activities related to dental appliances can fall under one of the following regulatory pathways.

Use or preparing for use of medical devices

54. The list of controlled activities does not include the use of a medical device; accordingly using a medical device is not a controlled activity.

55. Furthermore, the definitions relating to some controlled activities specifically exclude some of the activities involved in the preparation of and use of medical devices for specific patients.

56. For example, the definition of "manufacturing" in relation to a medical device [s34(3)] states that:

If a medical device has been supplied by its responsible manufacturer as being in its final state but needs to be prepared for use, preparing it for use is not part of manufacturing the device if the preparation—

(a) is done in accordance with the responsible manufacturer's product information; and

(b) does not constitute remanufacturing the device.

57. Similarly, s42(3) states that "*supply does not include…..using a medical device…. on a patient."*

58. Section 46(1) then states:

(1) To use a medical device….means to do either or both of the following:

(a) prepare the device …for use:

(b) use the device ….for a therapeutic purpose in, on, or in relation to, a person….

(2) In relation to a medical device….., to prepare for use includes the following:

(a) to assemble the device….:

(b) to calibrate or adjust the device …. before putting it into service or for a particular patient."

59. The intention seems to be that the activities underlined in paragraph 58 are not considered controlled activities, regardless of who carries them out. These activities are likely to be considered supply chain activities [s44(1)], and must be undertaken in accordance with the relevant regulations [s55(1)].

60. It is worth noting that the supply chain activities listed in s44(1) only include *use* of a medical device, not *prepare for use*.

61. We believe that many of the activities that were set out in paragraph 39 undertaken by dentists, dental specialists, dental technicians and clinical dental technicians would be considered as *prepare for use* or *use* of a medical device and captured by ss 46, 42(3) or 34(3); but not all of the activities related to dental appliances will fall within these provisions.

62. By example, we do not believe the design and making of a dental appliance would fall under the meaning of *prepare for use*, and will therefore be considered manufacturing - a controlled activity with different obligations.

63. For those activities performed by oral health practitioners that are considered controlled activities, the following regulatory pathways will apply.

Authorisations under subpart 3 of Part 3

64. Subpart 3 of Part 3 describes the authorisations to various sub-groups to perform controlled activities.

65. Section 75 allows for the manufacturing of custom-made medical devices (it is assumed that custom-made medical devices will be considered unapproved within this context). This provision is not limited to health practitioners.

66. This provision requires:

- meeting the regulations for a person who may manufacture; and
- the device be—
  - manufactured at the request of a health practitioner for a patient of that practitioner; and

- custom-made to meet the needs of that patient; and
- the person complies with any requirements specified in the regulations.

67. We do not know what the regulations and compliance for a manufacturer would be, or whether these would be tailored for different levels or types of manufacturing.

68. Section 62(3) provides for a health practitioner to supply an unapproved medical device by non-wholesale supply under the following conditions:
    - the device is relevant to a health service that forms part of the practitioner's scope of practice; and
    - the device is supplied—
        - to a patient of the practitioner; or
        - for a patient of, and at the request of, another health practitioner whose scope of practice includes the same health service; and
    - the patient is in New Zealand or is ordinarily resident in New Zealand; and
    - there is a complying special clinical needs supply authority for the patient for that device.

69. It appears that the ability for health practitioners to import an unapproved medical device, on behalf of the patient, is under a special clinical needs supply authority [s64(2)].

70. Oral health practitioners have not required a special clinical needs supply authority to supply or import dental appliances. The use of special clinical needs supply authority is not common practice at the moment.

71. The requirements of a special clinical needs supply authority are articulated in s64. The Bill's regulations will specify which classes of health practitioners may or may not issue a special clinical needs supply authority, and the circumstances in which these would be allowed.

Approval-exempt products

72. Section 114(1) allows the Regulator to declare a therapeutic product to be an approval-exempted product.

73. The Regulator can declare a class of products approval-exempted and specify the persons who are the sponsors of those products [s115(1)(b)]. These products do not have to be individually assessed [s115(2(b)(ii)].

74. It appears that dental appliances could apply to be approval-exempted by the Regulator, and the product sponsors defined as registered oral health practitioners allowed by their scope of practice to perform any of the related controlled activities (as defined in s53(2)).

75. We have the following concerns relating to the monitoring and compliance of approval-exempted devices, as it applies to dental appliances:

    - Obligations relate to a single sponsor (i.e. the oral health practitioner), but multiple individuals or parties are involved in the final delivery of the medical device.

    - Compliance relates to product standards and regulations, and approval-exempted products are included in these requirements [s117 & 118]. Although compliance is not yet defined, these obligations would most likely be new for oral health practitioners.

- Assurance of product standards and associated regulations by the oral health practitioner (sponsor) during all these steps will not be possible, particularly when it involves international third parties.
- Section 116(3) specifies that the sponsor would be held liable and could be convicted for non-compliance. However, monitoring compliance would be impractical, and most likely unachievable.

Summary of regulatory framework options for dental appliances

76. Based on our interpretation, we believe that oral health practitioners involved in supply chain or controlled activities related to dental appliances would fall under one or more of the following regulatory pathways and associated compliance obligations:

- prescribe, prepare for use, use (which will include trail fit, fit and implant) and repair:
  - meeting supply chain regulations (under the exemption of s46(1) for use and prepare for use of medical devices to not fall under the meaning of manufacturing)
- supply:
  - supplying an unapproved medical device to a particular patient under a special clinical needs supply authority [s62(3)]

    It may become difficult to determine when a dental appliance was used vs supplied. For example, if a mouth guard was sold without any modifications, would that be considered supply and require a special clinical needs supply authority (if the mouthguards was an unapproved product)?
- design and manufacture:
  - manufacturing a custom-made medical device for a specific patient, and meeting regulations of whom can manufacture and other compliance regulations [s75]; or
  - apply for a particular dental appliance or dental appliances as a group to be considered approval-exempted medical devices, with an “approved” sponsor (most likely an oral health practitioner) having to meet the sponsor criteria, product standards and regulations [s114-118]

    It is unclear how and by whom a decision would be made which section would apply.
- import:
  - importing an unapproved medical device, on behalf of a patient, under a special clinical needs supply authority [s64(2)].

77. As noted earlier, we envisage that activities of most dentists and dental specialist associated with dental appliances would fall under the prepare for use and use criteria of s24(1), particularly if they do not manufacture the dental appliance themselves.

78. We are keen to get clarification on whether the design and “making” of dental appliances by a dental technician, clinical dental technician, dentist or dental specialist would be considered manufacturing.

79. We want to highlight the following concerns relating to the regulatory pathways described in this section (paragraphs 47 – 76):

- how will compliance be effectively and equitably monitored?

- monitoring all the stages of the manufacturing or supply chain for these types of appliances, especially where a number of players are international, will be difficult
- any device approval processes or requirement for a special clinical needs supply authority may delay delivery of care to patients
- increased regulatory obligations may lead to price increases of dental appliances due to increased obligations on practitioners
- currently, most dental appliance costs are covered by patients rather than being funded by the public health system. Increased costs for dental appliances could be passed on to patient, which may adversely impact access to patients.

vi. Dental appliances can be manufactured by unregistered individuals

80. Currently there is no requirement in New Zealand for a practitioner to be registered to perform the activities of a dental technician. The title is protected under the HPCAA, but individuals can perform these activities if they do not call themselves a dental technician and do not perform restricted activities. Details of dental appliances that dental technicians can make are set out in Appendix A.

81. It appears that for non-registered individuals manufacturing dental appliances, the available regulatory pathways are those described above (for use or preparing for use of medical devices or approval-exempted products), except for the authorisations given to health practitioners in ss 61-65.

82. These individuals will not fall under the HPCAA, or any associated ethical and clinical standards. Their obligations will be defined in the regulations and rules of the Bill.

vii. Other medical devices used in dentistry

83. The definition of medical devices in the Bill is very broad. Oral health practitioners use a range of devices, equipment, materials and software that may fall under this definition and it is unclear at this stage how much of these products will be covered by the Bill. We understand this will be determined by the further details that will be developed to support the Bill.

84. The range of products used in dental practices and laboratories are extensive and diverse, and they each pose varying levels of risk to patients.

85. For example, on the lower scale of risk are items such as a dental chairs and lights, instrument trays, mouth rinse, examination mirrors, retractors, intra- and extra-oral cameras. Items with slightly higher risks include personal protective equipment and blow torches through to more invasive or higher risk instruments such as x-ray machines, pluggers, scalers, lasers, burs, curets, forceps, files, scalpels and so on.

86. We do not believe that all of these products should be, or will be, defined as medical devices. However, without a clear definition or further guidance we draw your attention to the broad possible interpretation of medical devices and submit that exempting some equipment from this definition should be considered.

87. We believe that a pragmatic, risk-based approach for the regulation requirements of medical devices is critical, particularly as the initial approval process for such devices has not been previously regulated in New Zealand.

88. As noted in our introduction, we are concerned that patient care will be adversely impacted by possible disrupted access and increased costs of medical devices commonly used in oral health practices that may be regulated under the Bill.

Dental materials

89. Oral health practitioners use dental materials that may fall under the definition of therapeutic products, either under medical devices or active medicinal ingredients.

90. Examples of these include composite materials, including amalgam, gold, cobalt–chromium, and titanium.

91. We are not clear whether all these materials would be regulated, and under which definition. Further the impact of such regulation on oral health practitioners and their patients is also unclear.

Software

92. We note that s34(2) also includes software that is used for therapeutic purposes. Dentistry has a number of software packages that are used as part of treatment planning, diagnosis and monitoring. Most of these are international products.

3D printing

93. The sector has also seen an increase in the use of 3D printing technology. One example of this is the use of CAD CAM in designing and manufacturing of dental crowns.

94. However, with the technology becoming cheaper and more accessible it is expected that the use of this will technology in the oral health sector will increase.

95. We are aware of online examples where individuals print (i.e. manufacture) their own dental appliances, such as dental retainers and braces.

96. Given the possibility of adverse health risks, quality assurance for 3D printed products for oral use will be important but very difficult to regulate effectively.

viii. Requirement of a pharmacy licence for health practitioner prescribers who supply and dispense medicine to patients

97. Section 61(1) now extends the non-wholesale supply of approved or approval-exempted category 1 or 2 medicines to health practitioner prescribers, if:

- the practitioner is a prescriber of the particular medicine; and
- the medicine is supplied to their own patient, or
- for a patient of, and at the request of, another health practitioner prescriber of that medicine; and
- the patient is in New Zealand or is ordinarily resident in New Zealand.

98. Section 61(2) allows a health practitioner to non-wholesale supply approved or approval-exempted category 3 medicines to patients as long as the medicine is relevant to their scope of practice, and under the same conditions as described in the last three bullets of paragraph 97.

99. Section 61(5) then provides for the dispensing of approved or approval-exempted medicine (all categories), under the same circumstances as set out in s61(1).

100. Both supplying and dispensing medicines are controlled activities defined under s53(2). This means these activities cannot be performed without authorisation. It is assumed that authority for health practitioners to perform these controlled activities is granted by sections 61 to 70 of the Bill.

101. Furthermore, both dispensing and supplying (categories 1,2) medicines are defined as pharmacy business activities in s36(1) of the Bill.

102. However, s36(2) excludes a professional practice of a health practitioner or veterinarian in which medicines are dispensed or supplied under the authorisations provided by sections 61 to 70, from the definition as a pharmacy business.

103. We are unable to identify any licence requirements for the health practitioner's practice (excluding pharmacists) where medicines can be supplied or dispensed.

104. We are unclear from the consultation document why a distinction has been made between premises where the same clinical activity of supplying and dispensing medicines occurs. Both supplying and dispensing are controlled activities and considered core pharmacy-related activities.

105. The Council supports good dispensing practice standards to all patients, regardless of where the activity occurs. Common ethical and professional standards and legal obligations should apply to achieve the objectives of patient safety, appropriate clinical care, and equity across health practitioners performing the same clinical activity - especially under a single piece of legislation.

106. Licence obligations can be tailored to apply across all dispensing facilities based on the type of pharmacy-related activities that will occur within the facility. This is not too dissimilar to different pharmacy service delivery models that currently exist.

ix. Category 3 medicine supply by health practitioner's staff

107. Section 65(1) allows a person who works for a health practitioner prescriber to supply a category 3 medicine to a patient of the health practitioner, under general supervision of the health practitioner.

108. We are unclear about the rationale for this new provision.

109. A category 3 medicine has some potential risks to patient safety, reflected through its classification and is not a general commodity.

110. There is no training, or any other professional or ethical standards that apply to the supply of category 3 medicines by health practitioner's staff.

111. General supervision does not appear to be defined.

112. As currently presented, the Council does not consider this provision will ensure safe and appropriate dispensing practice to patients in New Zealand.

113. Wherever possible, non-general sale medicines should only be dispensed and supplied by health practitioners with the necessary skills and with the necessary safeguards and standards in place to ensure appropriate patient care.

x. Supply of medicines vs dispensing

114. In our view the Bill takes a very narrow view of dispensing. Even to the extent that dispensing is defined as being part of manufacturing of medicine (s29), and for this reason is not explicit in the purpose of the Bill.

115. The Bill does not appear to recognise the importance of several aspects of appropriate dispensing practice such as:

- reviewing whether the medicines are appropriate and prescribed correctly for the specific patient taking into consideration the full medicine use profile (including supplementary, natural or other health product use, medical conditions, age, weight and so on)
- ensuring the correct medication is given to the patient
- ensuring that the patient understands how to take the medication correctly and is aware of potential side effects
- answering any related questions to ensure optimal patient compliance for a better outcome.

116. This approach is reflected in some of the new provisions of extending the "supply" of medicines to patients by other health practitioners, and in the case of category 3 medicines by practice staff, without any acknowledgement of specific competencies required for dispensing medicine to patients, associated ethical and professional standards, and other related obligations.

117. The Council understands the need for ensuring appropriate levels of access to medicines, but the Regulator must also ensure appropriate dispensing to patients and promote good dispensing practices.

xi. Controlled activities

118. The controlled activities listed in s53 do not make specific mention of advertising, promoting or marketing of therapeutic products. As these activities occur at various stages of the supply chain, consideration should be given as to whether they require specific mention in the list of controlled activities.

119. We note that the non-wholesale supply of medical devices is not listed as a controlled activity, only *supply-restricted device contrary to supply restrictions*.

120. As the manufacturing of some products will now fall under the Bill's definition of a medical device, and are restricted activities to be performed by registered health practitioners[1], this may have to be added to the list of controlled activities (unless the Regulator considers it necessary for any such product to be categorised as a supply-restricted device).

[1] For example a dental appliance

Part 4: Product approval

B1 Please provide any comments on the sections covering product approval requirements (ss 94–104).

121. Please refer to our comments in paragraphs 17 – 21, and 37 – 96.

B15 Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115)

B16 Please provide any comments on the sections covering sponsor obligations (ss 116–119)

122. Please refer to our comments in paragraphs 72 – 75.

Part 5: Licences and permits

B18 Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).

123. Please refer to our comments in paragraphs 29 – 31, and 97 – 106.

Part 6: Regulator

B24 Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182)

B25 Please provide any comments on the regulator's investigative powers (ss 183–196)

124. Please refer to our concerns expressed in paragraphs 22 – 28.

Part 8: Administrative matters

B33 Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285)

125. The Council agrees with the proposed amendments to the HPCAA (following acceptance by Parliament on Tuesday 9 April 2019) to include the authorisation of prescribers and issuing of standing orders into the scopes of practice.

126. Please refer to our comment in paragraph 35 about the consistency of the definitions for prescribers, registered health practitioners and scopes of practice.

Chapter C

C2 Please provide any comments on the approach for medicines categorisation (classification)

127. The Council supports the approach for the medicine categorisation.

128. The Council notes that some of the administration provisions for specific practitioner groups (including for oral health practitioners) will be removed from the medicines classification schedule and will be listed in regulations. In our view, this would mean medicine classification can be updated more readily and we are consequently satisfied with this proposal.

129. Although not technically an issue related to the Bill, we would like to take this opportunity to emphasise two classification discrepancies for dental related products.

- The first matter relates to fluoride varnish products used within dentistry. There are currently unapproved fluoride varnish products available in New Zealand. A regulatory loophole appears to exist between the way these products are handled in Australia and New Zealand. The scenario causes confusion for oral health practitioners, and some are unknowingly using unregistered fluoride varnish products because they are available from reputable dental suppliers. There is no reason for practitioners to suspect that the products they are sourcing are not an approved medicine in New Zealand.

- The second issue relates to hydrogen peroxide, and its use for tooth whitening. Hydrogen peroxide is classified as general sale medicine by Medsafe. However, in July 2011 the Environmental Protection Authority divided tooth-whitening products into the following three categories:
  - Products containing or releasing less than 7 percent hydrogen peroxide is for general sale.
  - Products containing or releasing between 7 to 12 percent hydrogen peroxide can only be supplied to and administered by a dentist, a registered oral health practitioner, or a non-registered tooth-whitening practitioner who is under the supervision of a dentist.
  - Products containing or releasing more than 12 percent hydrogen peroxide can only be supplied to and administered by a dentist, a registered oral health practitioner or a non-registered tooth-whitening practitioner who is under the supervision of a dentist.[2]

The discrepancy in classifications is causing confusion and creates a regulatory loophole.

130. We hope that these discrepancies can be addressed as part of this regulatory overview. We believe Medsafe is aware of both of these matters.

[2] https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/2017-Group-Standards/Dental-Products-Oxidising-5.1.1-Group-Standard-2017-HSR002557.pdf and https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/2017-Group-Standards/fe90667bdb/Dental-Products-Subsidiary-Hazard-Group-Standard-2017-HSR002558.pdf

C14 Please provide any comments on the transition arrangements for product approval controls for medical devices.

C15 Please provide any comments on the transition arrangements for regulating activities involving medical devices.

131. Schedule 1 clause 33 permits a 6-month temporary licence for medical devices at the commencement of the Act.

132. The Council is concerned that this timeframe may be insufficient, given the potential volume of medical devices that may require approval.

133. Dependant on the threshold of regulation for medical devices, this period may have to be reconsidered, or licensing staged based on risk profiles.

C43 Do you have any comments on the arrangement for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?

134. The Council supports the proposal to update the relevant scopes of practice to reflect the ability for a health practitioner to prescribe and issue a standing order.

135. The Council also notes the requirement for the Minister of Health to approve the prescribing activity within a scope of practice.

136. The Ministry of Health are included in the consultation process with the health regulator at the creation or amendment of any scope of practice. It is unclear why this particular clinical activity is separated for the Minister's approval. However, we do not object if this remains.

137. We note that the Minister may choose to delegate this function to the health regulator.

C44 Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?

138. The Council supports a consistent approach to the prescribing provisions within the scopes of practice. We prefer a more principle-based approach, rather than a defined medicine list. Such defined lists, if necessary, could be held in sub-ordinate legislation by the health regulator, as long as it is easy for a pharmacist, or other dispenser, to identify whether the medicine prescribed is within the practitioner's scope of practice.

139. The Council also proposes common competencies and performance measures, and shared professional standards related to prescribing and dispensing.

C45 Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.)

140. We have no specific concerns on the updated standing order provisions.

141. Auditing can be difficult to achieve regularly and consistently, but the Council acknowledges that auditing is both important and necessary.

C46 What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?

142. A number of therapeutic products are regularly used for treatments not approved on registration of the product.

143. Clinicians make these clinical judgement calls on a case-by-case basis and should be able to justify their decisions if an adverse event occurs.

144. For this reason, the Council agrees that a health practitioner prescriber could issue a special clinical needs supply authority for an approved product, as long as it is within their scope of practice.

C47 What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that:

- only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product
- other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?

145. The Council sees no reason for medical practitioners to be required to review the appropriateness of a clinical needs supply authority of another health practitioner. There is no guarantee that the medical practitioner would have the necessary knowledge or experience to make an informed decision. Also, the medical practitioner may not have all the patient-specific information available to make such a call.

146. The Council believes that if the product is within the health practitioner prescriber's scope of practice, that practitioner should make the choice of whether an unapproved product is appropriate for a specific patient, or not – regardless of whether it is approved or unapproved in New Zealand.

147. Similar to approved products, the clinician makes the clinical judgement, and must ensure that they have the appropriate information, knowledge and experience to make an informed decision. If not, they should consult other experts or refer the decision.

C48 In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?

C49 Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?

148. The Council cannot comment about specific quantities or frequency of supplying medicines to another health practice (we do not interpret this question relating to supplying or dispensing for

personal use). The example used in the consultation document, out-of-stock scenarios, occur. We believe this provision is appropriate.

149. Appropriate record keeping and monitoring of the type of medicine is essential.

150. Health practitioners have an obligation to act ethically and professionally. If they suspect that something unprofessional or illegal, then it is their responsibility to decline to supply the medicine and report the suspected activities if relevant.

50	Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?
C51	Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to the patients of the practice? What are the benefits and/or risks of allowing this?

151. Please refer to comments in paragraphs 97 – 113.

Appendix A – type of dental appliances that can be made by registered dental technicians

Dental technicians can design, manufacture and repair of fixed and removable oral and extraoral appliances and prostheses prescribed by a practising dental specialist, dentist, clinical dental technician, medical practitioner or other practising health practitioner. These include[3]:

- complete removable dentures and overdentures
- removable partial dentures including precision attachments
- fixed and removable orthodontic appliances
- crowns and bridges including precision attachments on natural teeth and implants
- implant overdentures and implant supported dentures
- tissue and implant supported maxillofacial, ocular and auricular appliances and prostheses, and other appliances and prostheses involved in the overall prosthetic rehabilitation of patients.
- specialist treatment appliances such as, but not limited to: diagnostic stents and radiographic stents, appliances for the treatment of temporomandibular disorders, appliances for the treatment of speech disorders, appliances for the treatment of sleep disorders and appliances for the treatment of audio disorders.

[3] https://www.dcnz.org.nz/i-practise-in-new-zealand/dental-technicians/scope-of-practice-for-dental-technicians/