MEMORANDUM TO DHA MEMBERS

Introduction

1) The Therapeutic Products Bill 2022 (**Bill**) aims to assure New Zealanders of the safety, quality, and performance of therapeutic products that are used in healthcare delivery (such as medicines and medical devices); and to ensure that the regulation of products imported and supplied in New Zealand aligns with international standards and best practice. If the Bill is passed, it will replace most aspects of the Medicines Act 1981 (with only the pharmacy ownership rules remaining) and revoke the Dietary Supplements Regulations Act 1985 (which regulates natural health products).

2) This Bill introduces the concept of regulating "Software as a Medical Device" (**SaMD**) in New Zealand.[1] It defines SaMD as a medical device that consists only of software (e.g., breast cancer detection software). If an individual or company develops or supplies SaMD products, then the Bill requires that the product must receive market authorisation or other permissions before it can be imported into, exported from or supplied in New Zealand. The Bill specifically addresses what importing, exporting and supplying[2] means in the context of software, as compared to more physical items (such as medicines).[3] The Bill imposes significant penalties for non-compliance.

3) Through this memo we aim to provide you, as a DHA member, with an overview of how the Bill proposes to regulate SaMD. Hopefully this will assist you to make an informed decision on whether you want to make a submission to the Health Select Committee or contribute to a DHA submission. Note: - It is possible that the future regulations and guidance may clarify some of the unclear matters in the Bill that this memo highlights. However, you may want to make a submission to encourage clarification of the issues highlighted whether through amendments, or the future regulations and guidance.

4) Submissions to the Health Select Committee are open until **15 February 2023**. You can make a submission here. Any submissions will be publicly released on the Parliament website. The report of the Select Committee summarising submissions will be available from 14 June 2023.

5) You may want to consider your submission at two levels:

    a) who the definition of SaMD should apply to - currently, the definition of SaMD is broad and so may unintentionally catch many developers and suppliers of health software. You may consider if it would be beneficial for the application of SaMD to align with the Australian position (discussed below);

[1] All parties except for the Māori Party voted that this Bill should be moved to a First Reading before the House of Representatives. During the First Reading, SaMD was not discussed in detail. The move to regulate SaMD in New Zealand is consistent with Australia. Europe and United States also have established strict requirements for software that is a medical device.
[2] Clause 67.
[3] Clause 40 of the Bill acknowledges that software is not a physical thing and defines importing software to mean making it available for use by persons in New Zealand. Clause 39 conversely defines exporting in the context of software to mean making it available for use by persons outside of New Zealand.

b) what approach the Bill should take to regulating SaMD and in what aspects it should differ to the standard approach taken in regulating medical devices because of the nature of software and the software industry.

(a) Who will the definition of SaMD apply to?

6) The Bill will apply to any individual or company that intends to import into, export from, manufacture or supply SaMD in New Zealand. The definition of SaMD applies to any software developed for humans that is intended to be used for a therapeutic purpose as defined under clause 15 of the Bill (see Appendix A). The Bill's proposed definition of therapeutic purpose is much broader than the existing definition under the Medicines Act 1981, and clause 15(g)-(l) of the Bill are new definitions that may capture members developing or supplying any kind health-related software. We suggest that you consider the definitions carefully as they will determine whether your business falls within the ambit of the regime.

7) The proposed definition of 'therapeutic purpose' is also much broader than the definition in the Therapeutic Goods Act 1989 in Australia. For example, therapeutic purpose now extends to "maintaining and promoting human health", "investigating a human physiological process" and "supporting or sustaining human life" which could capture software for an array of consumer health products. For example, this could apply to fitness, general wellbeing, and digital mental health apps.

8) The Australian Government's guidance on SaMD excludes consumer health products that do not provide specific treatment or treatment suggestions; digital mental health tools including cognitive behavioural therapy tools; and enabling technology that is intended to support telehealth and remote diagnosis. While we would expect the New Zealand Government to release similar guidance, you may wish to make a submission that informs the Select Committee about any issues that the industry might have if the narrower Australian approach is not adopted.

9) One way the Bill acknowledges the risk of disproportionate regulation is by prohibiting the Minister from recommending regulations for therapeutic products in certain circumstances. If the likely risks associated with the product are so small that regulation of it is unnecessary, or the product is regulated by other means, the Minister cannot recommend regulations for that therapeutic product.[4] This may act to restrict the definition of therapeutic purpose when determining if specific software meets the threshold for SaMD. Although there are also exemptions to the application of the Bill,[5] an exemption would require an applicable individual or company to obtain a permit.

[4] Clause 19.
[5] Clause 379.

Personalised medical devices

10) SaMD may also fall under the definition of a personalised medical device depending on its degree of personalisation and how it is produced. If SaMD falls within the definition, it may be subject to additional manufacturing or supply restrictions (which we set out at paragraph 20). Since the explanatory note of the Bill only provides examples of tangible personalised devices, it is not clear if this definition and its associated obligations will apply to SaMD. The Bill sets out three different groups of personalised medical devices which may apply to SaMD:[6]

    a) an adaptable device – if it is developed as a standard device and intended to be configured to suit each patient at the point of care. It is unclear if this includes software that is configured by the practitioner by entering patient metrics such as weight and height;

    b) a patient-matched device – if it is developed using a standard production process for a specific patient and their circumstances. 'Standard production process' is not currently defined but may be more relevant to the manufacture of tangible products rather than SaMD;[7] or

    c) a custom-made device – if it is developed from scratch on a case-by-case basis to meet the specific patient's needs.

Manufacturers and developers of SaMD

11) A person "manufactures" SaMD when they do anything that is part of developing the software.[8] Where the previous manufacturer supplies SaMD in its final state, a person "remanufactures" when they make a major change to the SaMD which would have a significant impact on its safety, quality, or performance.[9] A remanufacturer will become the responsible manufacturer under the Bill and have associated obligations (see Market Authorisation section below). It is not clear whether the common practice of a local entity configuring overseas-standardised software for NZ use or for a specific customer's use in NZ would cause the local entity to become the responsible manufacturer under the Bill. To the extent that this is a concern, you may consider seeking clarification of who is intended to fall within this part of the regime.

[6] Clause 25.
[7] We consider it unlikely that this would apply to software as software does not typically undergo a 'standard production process'.
[8] Clause 44(1)(d).
[9] Clause 46.

(b) How will the Bill impact those that it applies to?

12) If your software is a SaMD, then the Bill will regulate how you may supply, import or export your product. It requires that all therapeutic products obtain market authorisation or other permissions from the Therapeutic Products Regulator (**Regulator**), before it can be imported into, exported from or supplied in New Zealand.[10] The associated fees and levies of an individual or company applying for such permissions will be specified, following public consultation, in regulations made under the Bill.[11]

13) The Bill introduces a system of market authorisations, licences, permits and standing permissions. Suspending or cancelling such permissions could have a significant impact on the interests of an individual or company. This system will be overseen by the Regulator who will be responsible for issuing market authorisations, licences and permits, monitoring compliance, and enforcing compliance with the Bill. As part of this, the Regulator will maintain a publicly available Therapeutics Products Register of all therapeutic products. The Register will specify if the product has market authorisation and any applicable licences and permits.

Therapeutic Products Regulator

14) The Bill introduces a new Regulator that will have broader compliance and enforcement powers than the existing regulator, Medsafe. The Regulator will be a branded business within the Ministry of Health and will have an independent statutory officer appointed to head the unit.[12] During the First Reading of the Bill,[13] the Minister of Health stated the intention of this change was to give the Regulator more regulatory tools to ensure timely and safe access to therapeutic products. It is unclear if the Bill will achieve this efficiency or create more hurdles that stifle innovation as an unintended consequence. The Bill does not specify any oversight or procedural checks on the Regulator's powers which may be of concern to you and the health sector in general. While we suspect other groups will make submissions on this, you may want to address this in your submission.

Market Authorisation

The process for obtaining market authorisation is set out in Part 4 of the Bill. In the case of SaMDs, an applicant[14] who proposes to import, export or manufacture (develop)[15] a medical device must satisfy the Regulator of the product's safety, quality and performance for its intended authorised indications.[16] The evidence that the Regulator will consider as

[10] Clause 67.
[11] Part 9 Subpart 2.
[12] This means the Regulator will act independently of the chief executive of the Ministry of Health and the Minister of Health but may be subject to general policy directions.
[13] First Reading of the Bill (Part 1).
[14] Clause 121 specifies the criteria for being a sponsor/applicant of a medical device.
[15] An applicant may also include a remanufacturer of a SaMD.
[16] Clause 120.

part of its evaluation will vary depending on what is appropriate and proportionate in the circumstances having regard to the likely benefits and risks associated with the product.[17]

15) If satisfied with its evaluation, the Regulator may issue the applicant, who at that point becomes the sponsor of the product, with either a standard, provisional or export authorisation.[18] Standard authorisations will not lapse unless cancelled.[19] Provisional authorisations are limited and will lapse after a maximum of two years.[20] The Regulator can also impose conditions and vary the authorisation.

16) If an authorisation is granted, the sponsor will be responsible for ensuring that the product conforms to the authorisation and applicable product standards.[21] There are also ongoing obligations for the sponsor to: maintain a post-market surveillance and response system; keep records; and comply with reporting requirements.[22] Failure to obtain and comply with market authorisation where required may expose individuals and companies to significant penalties.[23]

17) Subsequent minor changes to a product will be covered by the original market authorisation but major changes that significantly impact its safety, quality, or performance, will require new market authorisation.[24] The sponsor must also notify the Regulator of minor and major changes if required under the rules.[25] Since the rules have not yet been released, it is unclear what kind of changes to SaMD would require notification. Although unlikely, it is unclear at this stage if the rules about minor changes will include small bug fixes. Given the frequency of modifications in software compared to traditional products, it may be appropriate to consider addressing what should not require notification, and perhaps suggesting a different threshold or a different regime for SaMD in your submission.

Other Restrictions

18) Controlled Activities - The Bill also regulates who is allowed to carry on 'controlled activities' and how those activities are carried on. These activities include developing, exporting, supplying SaMD and clinical trials.[26] A person may not carry on a controlled activity unless a licence, permit or provision of Part 3 Subpart 3 of the Bill allows them to do so. Anyone permitted to carry on a controlled activity must comply with the requirements set out in the rules or regulations, which may relate to matters such as

[17] Clause 119.
[18] These authorisations will replace standard and provisional consents under the Medicines Act.
[19] Market authorisations may be cancelled under clause 136 and 137 of the Bill.
[20] Clause 120(e).
[21] Clause 9. The Regulator may also establish product standards rules that will specify the minimum standards a product must meet before market authorisation can be issued.
[22] Part 4 Subpart 2.
[23] Clause 247.
[24] Clause 128(1)(b).
[25] Clause 144
[26] Clause 69 lists these controlled activities.

product and consumer information, packaging, security and auditing.[27] If a developer of a SaMD wants to conduct a trial to investigate the safety and performance of a SaMD on individuals, there is a risk that this may be considered a clinical trial. If it is, then there may be additional licence requirements such as ethics approval.[28] You may want to consider a submission on the restrictions set for controlled activities as they apply to SaMD.

19) Supply or use restrictions - The Regulator can establish supply or use restriction rules for medical devices, such as SaMD.[29] The explanatory note of the Bill acknowledges that the nature of these restrictions will vary considerably under the rules and there will be many products for which no restrictions will apply. You may wish to consider making a submission on the rules that may restrict the use and supply of SaMD.

20) Personalised Medical Devices - The Bill does not specify any additional requirements for adaptable or patient-matched medical devices but does recognise that manufacturers (developers) of custom-made devices may need the ability to develop their product without obtaining market authorisation.[30] As a result developers of custom-made devices are instead subject to stricter manufacturing (developing) and supply requirements. These requirements include that it must be manufactured (developed) on request by a practitioner of the patient, supplied only to that practitioner or patient, and in accordance with any applicable regulations or product standards.[31] Exports of custom-made devices are only permitted if the patient is ordinarily resident in New Zealand. You may wish to consider how your SaMD engages with customers and if it falls within the custom-made device regime. If it does, you may want to make a submission on how the manufacturing and supply requirements apply.

21) Misrepresentation and Advertising - There are limitations on how SaMD can be advertised and what kind of representations can be made about it. The Regulator may issue a recall order or direction and exercise enforcements powers in response to non-compliance.[32] The requirements for and distribution of an advertisement heavily rely on future regulations, as will any exclusions of what an advertisement is not. You may want to make a submission on what the restrictions of advertisement should or should not cover.

22) Improper Inducement - A sponsor or supplier of SaMD should be aware that they cannot give a benefit to a health practitioner to influence or reward them for making a favourable clinical decision about a SaMD.[33] It is unclear how this may affect business models of suppliers of SaMD. It is common for software licensing to include volume discounts. You

[27] Clause 72.
[28] Clause 165.
[29] Clause 27.
[30] Custom-made and patient-matched devices are non-wholesale products under clause 56(3)(a) of the Bill, and may be supplied by a health practitioner without market authorisation. However, in doing so, health practitioners will still need to abide by the requirements set out in clause 83(3).
[31] Clause 108.
[32] Clause 190 and 191 (misrepresentation); clause 193 and 194 (advertising).
[33] Clause 195.

may want to consider if your practices in relation to licensing might fall within the definition of improper inducement. Accordingly, submissions could address the operation of standard software licensing contracts or business models in the context of healthcare. Persons who breach this clause may be subject to the maximum civil penalty (specified below under *Enforcement*).

23) Tampering The Bill also prohibits tampering with SaMD.[34] This prohibits any interference that may adversely affect, or might be reasonably expected to affect, the use, safety, quality, or performance of the SaMD. The definition of tampering is broad enough to cover any change to a SaMD that affects its functionality and does not impose a threshold on what would qualify as tampering. If any person contravenes this section, as an individual they will be liable for a fine not exceeding $50,000 or will otherwise be liable for a fine not exceeding $250,000.[35] Tampering would likely include the introduction of any malware or viruses to the SaMD which would be a good thing. But is unclear if it would also include intentional modifications that impact on the operation of a solution simply because of unexpected bugs in the release. You may wish to clarify this in submissions and also specify any guidance on this point.

Enforcement

24) The Regulator may take a series of enforcement actions following any non-compliance.[36] Non-compliance may result in criminal and civil offences and in the suspension or cancellation of authorisations or other permissions.[37]

25) Offences involving knowledge or recklessness have a maximum penalty of 5 years imprisonment and a $200,000 fine for an individual and a $1,000,000 fine for a company.[38] Offences involving strict liability have a maximum penalty of a $100,000 fine for an individual and a $500,000 fine for a company.[39] The maximum civil penalty is a $250,000 fine for an individual and a $2,000,000 fine for a company. Non-compliance may also result in infringement offences (the fee set by regulations or the court[40]) and enforcement of undertakings.

[34] Clause 187.
[35] Clause 265.
[36] Part 8.
[37] Part 8 Subpart 2-5; and 8.
[38] Clause 247.
[39] See Part 8, Subpart 3 for all strict liability offences.
[40] Clause 277(2).

(c) What to include in a Select Committee submission

26) A submission is your chance to present your opinion, observations, and recommendations about the Bill to help the committee make an informed decision about the future direction of the Bill. You are only required to provide your name or organisation name on a submission. If there are any parts of your submission that is confidential, this should be discussed with the clerk of the committee.[41] If you would like to speak before the Committee in support of your submission, please indicate this in your submission.

27) The Parliament website provides several resources to help write submissions.[42] We have summarised a few tips below:

- About you - give a brief description of your organisation and its aims;
- General position - tell the Committee what you think of the Bill overall, are you in support of it, are there parts of it that you oppose (be specific with clause references);
- Detailed comments - provide recommendations about what you think should change. For example, you might want to suggest new wording for clauses;
- Be clear, concise, and present your ideas in an easy-to-read format;
- Be accurate – use and cite facts and figures to support your position; and
- Relevant – be specific about your concerns and use clause references to help the committee.

28) While this memorandum is limited to provide information about SaMD, your submission can address as many parts of the Bill that are of interest to you. You may want to obtain independent legal advice about this Bill or your submission; The DHA plans to make a submission on behalf of members raising the concerns outlined above. We are looking for feedback from all members and will setup a workshop to discuss the above. If you cannot make the workshop, you can still let us know if you have any concerns with the Bill by emailing us. Please also get in touch with us if the DHA making a submission on the issues above would be a concern for you.

[41] Health@parliament.govt.nz.
[42] See here for more resources: https://www.parliament.nz/en/pb/sc/how-to-make-a-submission/.

APPENDIX A

Key Clauses

29) Medical devices are defined under clause 24 of the Bill as:

> **24 Medical device**
> (1) A therapeutic product is a medical device if it—
>
> (a) is a therapeutic product under section 16(1)(a) or (b); and
>
> (b) achieves, or is likely to achieve, its principal intended action by means other than pharmacological, immunological, metabolic, or genetic means (although its function may be assisted by pharmacological, immunological, metabolic, or genetic processes).
>
> (2) A therapeutic product is also a medical device if the rules referred to in section 21 say it is.
>
> (3) However, a product referred to in subsection (1) is not a medical device if the rules referred to in section 21 say it is a different type of therapeutic product.

30) SaMD is defined under clause 26 of the Bill as:

> **26 Software as a medical device**
> (1) **Software as a medical device** means software that meets the definition of a therapeutic product without any associated hardware (other than an unrelated device that is needed solely to present a user interface).
> (2) Software is also **software as a medical device** if—
> (a) it is intended to be used to augment a product that is not a therapeutic product by making use of the functions, sensors, or other components of that product; and
> (b) the product and software together meet the definition of a therapeutic product.

31) Therapeutic Product is defined under clause 16 as:

> **16 Therapeutic Product**
>
> (1) Each of the following is a therapeutic product:
> (a) a product that is intended for use in, on, or in relation to humans for a therapeutic purpose:
> (b) a product that regulations referred to in section 19(1) say is a therapeutic product:
> (c) a product that is intended for use as an active **ingredient of a medicine.**
> (2) If 2 or more products—
> (a) are intended by the manufacturer to be used together; and
> (b) when used together, meet the definition in subsection (1),—
> those products together are a single therapeutic product (even if some or all of them separately would not be a therapeutic products).

32) Therapeutic Purpose is defined under clause 15 as:

15 Therapeutic purpose
The following are therapeutic purposes:
(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury:
(b) influencing, inhibiting, or modifying a human physiological process:
(c) testing the susceptibility of humans to a disease or an ailment:
(d) influencing, controlling, or preventing human conception:
(e) testing for human pregnancy:
(f) investigating, replacing, modifying, or supporting part of a human's anatomy:
(g) investigating a human physiological process:
(h) supporting or sustaining human life:
(i) providing vitamin, mineral, or other human nutritional supplementation:
(j) maintaining or promoting human health:
(k) disinfecting medical devices:
(l) a purpose connected with a purpose referred to in paragraphs (a) to (k).