



DHA

TE RŌPŪ
HAUORA
MATIHIKO

Digital Health Association

DHA SUBMISSION Therapeutic Products Bill 2022

MARCH 2023

Ryl Jensen - DHA CEO

Cara Maennchen - DHA General Manager

CONTENTS

Executive Summary	3
About the Digital Health Association (DHA)	6
Submission.....	7
The DHA supports the intent of the Therapeutic Products Bill 2022.....	7
The Importance of the Digital Health Industry to Aotearoa, New Zealand	9
Legislation arguments and potential unintended consequences of the Bill	10
1. The current definition of SaMD is too broad and should be reconsidered.....	12
2. There has been a lack of adequate consultation regarding SaMD.	13
3. Health software is already sufficiently regulated under existing legislation.....	14
4. The Bill does not adequately distinguish between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD).....	15
5. Concerns over the capability and capacity of the Regulator.	16
6. The Bill does not currently support the objectives of Te Tiriti o Waitangi relating to health software.....	17
7. The Bill does not currently harmonise with other jurisdictions relating to SaMD.....	18
8. The Bill could introduce significant compliance cost to health software companies.....	23
9. The Bill has the potential to stifle innovation and productivity of health software.....	24
10. The Bill does not consider the software development life cycle.	26
11. Legislation should be enabling to meet market and consumer demands.....	26
12. Legislation should consider the proportionate risk of True SaMD vs health software.....	27
Legislation Recommendations.....	28
Conclusion.....	39
DHA Member Submissions	40
Sense Medical.....	40
Best Practice	41
Cemplicity.....	43
Rush Digital	44
Sysmex.....	45
Medi-Map.....	47
Securely.....	49
Spritely	50

Enigma.....	51
Alcidion.....	53
Asia Pacific Healthcare Group (APHG).....	54
The Clinician.....	57
Healthpoint.....	59
Tunstall.....	60
Manage My Health.....	62
Just a Thought.....	64
References.....	65

DIGITAL HEALTH ASSOCIATION (DHA) SUBMISSION ON THE THERAPEUTIC PRODUCTS BILL 2022

EXECUTIVE SUMMARY

The Digital Health Association (DHA) is the digital health industry's peak advocacy body representing over 180 members from across Aotearoa New Zealand and internationally. This submission, presented to the Health Select Committee on behalf of its membership, details the importance of the health software industry to New Zealand, as well as presents feedback, arguments, and legislation recommendations regarding the Therapeutic Products Bill 2022 in relation to Software as a Medical Device (SaMD). At the conclusion of this submission are personal member submissions detailing how their specific organisations may be impacted by the Bill.

Years in the making, the Bill is a much-awaited piece of legislation. The DHA and its members support the overall intent of the Bill – to ensure therapeutic product legislation is up to date, fit-for-purpose, and to provide a mechanism to keep New Zealanders safe from harm relating to therapeutic products. However, the DHA believes that the problem the Government is trying to solve with the introduction of SaMD in the Bill is unclear.

The Bill addresses regulation of several different types of therapeutic products, including but not limited to medicines, natural health products (NHPs), medical devices, and SaMD. As a result, the Bill, and its definitions of what constitutes a therapeutic purpose, are broad and all encompassing, including in the intended regulation of SaMD.

The value of the digital health industry in New Zealand is significant and growing, as technology continues to transform healthcare delivery. The technology sector as a whole is touted to become the largest contributor to GDP by 2030. Digital health has also been identified as one of six key priorities in Te Pae Tata – Interim Health Plan 2022 to help transform New Zealand's health system as part of the recent health sector reforms.

The DHA's view is that greater regulatory oversight of software that is used on patients for purposes such as diagnosing, treating, preventing, or alleviating medical conditions, injuries and diseases, sustaining life, and investigating physiological processes is necessary and that the potential risks relating to that software ought to be monitored and controlled via enhanced regulation. We support the regulation of such software (which we call "True SaMD" in this submission).

Health software is very different, however, from True SaMD. Unlike True SaMD, health software does not diagnose, treat, prevent, or alleviate medical conditions, injuries and diseases, sustain life and investigate physiological processes. Many health software products do no more than facilitate patient-doctor communications and consultations and/or assist in practice management, and generally pose no more risk of harm to the patient than any other applications used to facilitate remote interactions (e.g., Microsoft Teams) or administrative functions at a medical practice.

Moreover, a distinction between SaMD and Software in a Medical Device (SiMD) is recognised by a number of key overseas jurisdictions, to account for the differences in relationship and function between health software and medical devices.

The DHA has serious concerns about the implications of the broad definition of SaMD, which will inadvertently include health software that is low risk in nature and should not necessarily be subject to

regulation. Additionally, the Bill does not currently align with risk-based regulation practice as demonstrated in other jurisdictions and as written, runs the risk of tying several therapeutic product verticals to a rigid and onerous regulatory framework.

The DHA believes that regulations should take into account the rapid rate of digitalisation and be able to keep up with this dynamic environment. Notwithstanding this, we think that the government has a unique opportunity before the Bill comes into force to create modern regulations that are adaptable, flexible, agile, and forward-thinking, thus creating a global benchmark for exemplary regulation. Critically, this must be led and supported by a capable Regulator with the capacity and expertise to regulate and make decisions on a wide range of therapeutic products. Given the current worldwide skills shortages and global economic and political uncertainty, the challenges posed in achieving this are significant.

In relation to SaMD, the DHA believes the following substantial unintended consequences could arise from the Bill:

1. An inability to achieve digital transformation in the health sector as identified by the Government in Te Pae Tata – Interim Health Plan 2022.
2. An impact on the Crown to fulfil its obligations under Te Tiriti o Waitangi regarding innovative digital solutions to aid improving Māori health outcomes.
3. Low-risk health software products being inadvertently caught by the broad definition of SaMD decreasing the productivity of the health software industry; health services who rely on developments to health software, would be measurably negatively impacted.
4. Many health software organisations could be forced out of business, thus effecting how the health system operates and New Zealand's economic growth.
5. Long lasting negative impacts on efficiency, R&D, innovation, and competition within the health software industry.
6. An increase in manufacturing and compliance costs of health software and this being passed onto health providers; the taxpayer would ultimately fund this cost.
7. Regulator overreach could impact the design and update process (the software development lifecycle) resulting in a poor user experience and a negative impact on health services.
8. Health software entities currently contributing to New Zealand's GDP and growth could be forced to move their operations offshore reducing the economic benefit of retaining suppliers in New Zealand.

Currently, the Bill will apply to most individuals or companies that intend to import into, export from, manufacture or supply health software in New Zealand. The DHA argues, however, that the Bill is trying to tackle regulation of products that are not normally grouped together and that consideration of this is imperative to future-proof the legislation. Following are some key arguments the DHA would like the Health Select Committee to address:

1. The current definition of SaMD is too broad and should be reconsidered.
2. There has been a lack of adequate consultation regarding SaMD.
3. Health software is already sufficiently regulated under existing legislation.
4. The Bill does not adequately distinguish between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD).
5. Concerns over the capability and capacity of the Regulator.
6. The Bill does not currently support the objectives of Te Tiriti o Waitangi in relation to health software.

7. The Bill does not currently harmonise with other jurisdictions relating to SaMD.
8. The Bill could introduce significant compliance cost to health software companies.
9. The Bill has the potential to stifle innovation and productivity of health software suppliers.
10. The legislation does not consider the software development life cycle.
11. Legislation should be enabling to meet market and consumer demands.
12. Legislation should consider the proportionate risk of True SaMD vs health software.

The DHA has provided arguments and legislation recommendations for the Health Select Committee to consider. Ultimately, we believe that significant consultation with the health software industry and changes to the Bill must happen in order to ensure that regulation does not stifle an extremely valuable and growing industry in Aotearoa New Zealand or affect health services and patients in a negative way.

The DHA looks forward to discussing our submission in-person with the Health Select Committee.

ABOUT THE DIGITAL HEALTH ASSOCIATION (DHA)

The Digital Health Association (DHA), previously known as New Zealand Health Information Technology (NZHIT), was formed in 2002 as a not-for-profit, incorporated society and is the peak advocacy industry body for the New Zealand digital health sector. The DHA represents providers from across the spectrum with over 180 member companies ranging from Small to Medium Enterprises (SMEs) to large multi-nationals with an interest in New Zealand’s health sector. We also represent a broad cross-section of healthcare providers, consultancies, legal, insurance, government, and regional agencies.

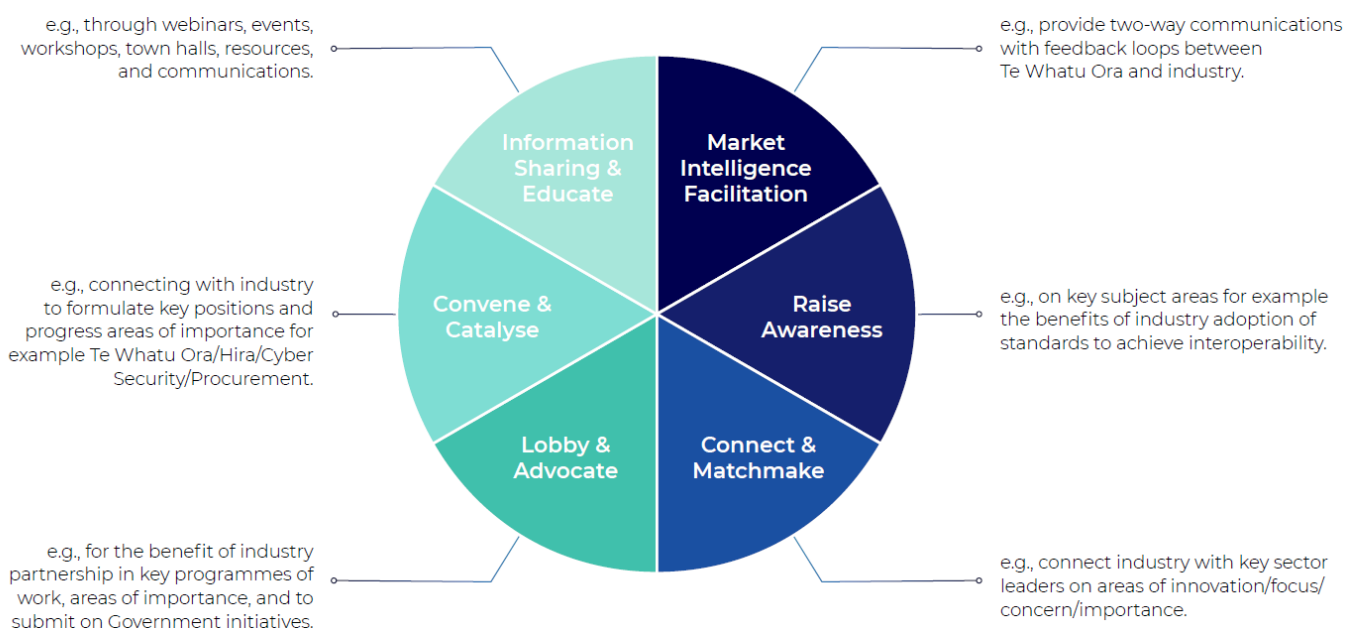
This strong network brings together custodianship of nearly 100% of Aotearoa New Zealand’s health-related data that covers a New Zealander’s health journey from birth to death. We work collaboratively across the health sector, with government, and with key stakeholders to position digital health technologies as critical key infrastructure and an enabler of quality health, social care, and wellbeing services. Our members make a significant contribution to, and investment in, the research, development, and implementation of innovative digital health solutions to support and enable the future direction of health delivery, both in New Zealand and internationally.

Our vision is to create a thriving and vibrant member community which makes a significant contribution towards “Enabling a Healthier Aotearoa New Zealand” through a world-class digital health ecosystem.

Our purpose is to be the conjugate between government and industry, to advocate for the uptake of digital health to improve health outcomes, and to provide an open environment that enables a coordinated, educated, informed, and strong voice that maximises social and economic value for New Zealand through digital health technology.

OUR PURPOSE AND FUNCTION

At a high level, we have created the following graphic to illustrate our role within the ecosystem:



SUBMISSION

The DHA supports the intent of the Therapeutic Products Bill 2022

The Therapeutics Products Bill 2022, (the Bill), is a much-awaited piece of legislation. The Bill intends to regulate how 'therapeutic products' are manufactured, tested, imported, promoted, supplied, and exported. This will involve, among a number of significant changes, the establishment of a new Regulator, a market authorisation regime, the regulation of natural health products (NHPs), a more robust offences and penalties regime, and most notably for the digital health industry, the introduction of regulation of Software as a Medical Device (SaMD).

Since the Bill was first introduced to Parliament, New Zealand has undergone a huge amount of change including vast technological developments, changes in government, and a global pandemic. With change of this magnitude, enormous complexity is introduced to a Bill of this breadth. This is particularly so for the digital health industry, which has seen technological advancements far beyond what the original intentions of the Bill could have foreseen. The COVID-19 pandemic accelerated advancements in the adoption of technology across health systems and highlighted the importance of an agile, enabled, and innovative health software industry to improve health outcomes and advance access to healthcare across Aotearoa New Zealand.

The DHA and its members welcome initiatives to improve regulation and patient safety and supports the overall intent of the Bill; to ensure therapeutic product legislation is up-to-date and fit-for-purpose to keep New Zealanders safe from harm as set out in the explanatory note, "to protect, promote, and improve the health of all New Zealanders by providing for the acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their life cycle" (New Zealand Parliament, 2022, p. 2). The DHA acknowledges that there will be some health software that will need to be regulated as SaMD, however, the DHA has significant concerns about the implications of the broad definition of SaMD as stated in the Bill and which will inadvertently capture health software that is low risk in nature and should not be subject to regulation of this kind.

The DHA believes that this definition has the potential to capture almost all health software currently operating in New Zealand's health system and that this could have far reaching unintended consequences such as reducing research and development (R&D), slowing down productivity, inhibiting economic activity, and stifling innovation in a growing and valuable industry to Aotearoa New Zealand. This will ultimately translate to the health consumer when regulation stands in the way of innovation and advancement of the health sector. As well as this, the Bill has the potential to place disproportionate compliance burden and cost on health software providers that, we believe, should not have otherwise been captured by the Bill.

In today's environment digitalisation presents great and unprecedented opportunities to enable the improvement of health outcomes of all New Zealanders and provide efficiency and monetary gains across the health system. The DHA acknowledges however, that there remains uncertainty of the evolution of such transformative technologies and the implications for society. We also acknowledge the challenges these technologies pose to rulemaking activities. The OECD states that these challenges can be broken down into four categories:

- i) The pacing problem where the sheer pace of technological change itself fundamentally challenges contemporary regulation.
- ii) Designing “fit-for-purpose” regulatory frameworks that meet Government’s needs, protect innovation and advancement of technology, and ensure consumer safety.
- iii) The regulatory enforcement challenges that question the traditional notion of liability and harm to the end user in relation to technology developments.
- iv) The institutional and transboundary challenges of traditional institutional frameworks underpinning regulations that may not be fit-for-purpose when applied to technology (OECD, 2019).

The DHA acknowledges that the Government has attempted to write legislation that is flexible and will move with changing environments however, the DHA would like to note that legislation, once in force, is typically very hard to change so policy settings should be enabling from the outset to ensure agility and flexibility in regulation to match market forces, consumer needs, and the pace of change, specifically relating to software. There is proven regulatory science that supports those products that have very short iterative development and life cycles which we encourage the Government to explore and apply to the Bill.

New Zealand has a unique opportunity to be world leading in effective and appropriate legislation and a role model to other nations in agile regulation. However, currently we risk falling behind by following not fit-for-purpose examples.

Following is the DHA’s submission on the Bill covering the importance of the digital health industry to the New Zealand economy, our arguments, potential significant unintended consequences of the Bill, and our legislation recommendations. Included at the end of the DHA submission are individual health software organisations’ own submissions describing the negative effects they anticipate the present draft of the Bill will have on their operations, products, and subsequently New Zealand’s health sector.

The DHA would be happy to speak to our submission, on behalf of our members, in front of the Health Select Committee.



Ryl Jensen
DHA CEO



Cara Maennchen
DHA General Manager

The Importance of the Digital Health Industry to Aotearoa, New Zealand

The value of the digital health industry in Aotearoa New Zealand is significant and growing, as technology continues to transform healthcare delivery. With the rising demand for personalised and remote healthcare services, digital health tools and products are playing a crucial role in improving patient outcomes, reducing healthcare costs, aiding access to healthcare services, and enhancing overall healthcare quality and efficiency. New Zealand is home to many innovative and world leading health software companies who contribute to the growth and advancement of New Zealand as a whole.

Furthermore, the health sector reforms and Te Pae Tata – Interim Health Plan 2022 lists developing “greater use of digital services to provide more care in homes and communities” as one of six key priorities to transform New Zealand’s health system (Te Whatu Ora - Health New Zealand, 2022, p. 6). This shows the level of commitment from government to utilise, enhance, and prioritise digital health and as a means to honouring the principles of Te Tiriti o Waitangi, providing more equitable care, and greater access to health services for all New Zealanders.

According to the New Zealand HealthTech Insights Report 2022, health technology companies in New Zealand generated \$2.9 billion in revenue in 2021, including \$269 million from digital health and health IT companies. The industry has seen rapid growth, with a 5-year compound annual growth rate (CAGR) of 12.1%. This growth is reflected in the increase in employment in the sector, growing by 21.9% in 2021 alone, with the sector now employing over 10,000 people globally including 6,383 in New Zealand (Technology Investment Network & Consortium for Medical Device Technologies, 2022).

Moreover, health technology exports from New Zealand have grown by 37.7%, demonstrating the potential for New Zealand companies to become leaders in the global medical device and digital health market (Technology Investment Network & Consortium for Medical Device Technologies, 2022, p. 7).

New Zealand digital health companies already have an impressive global footprint and reputation for innovation. DHA member Orion Health is internationally recognised for its expertise in interoperability and data exchange, enabling the sharing of critical health information across various health systems and Whānau Tahi is understood to be the world’s first healthcare management system founded on a culture-centric model (Technology Investment Network & Consortium for Medical Device Technologies, 2020, p. 17).

As well as this, companies in the Digital Health & Health IT category collectively invested 23.73 of their revenue into R&D, an indication of the pace at which these categories are pursuing innovation (Technology Investment Network & Consortium for Medical Device Technologies, 2022, p. 7).

In addition to revenue, employment, innovation, and R&D, the digital health industry in New Zealand has the potential to generate efficiencies and significant cost savings for the healthcare system. By leveraging digital technologies such as telehealth and remote patient monitoring, and those that improve clinical workflows, consumers will have greater access to healthcare services especially in rural areas, and healthcare providers can deliver care more efficiently, reducing the need for costly in-person visits and hospitalisations. The digital health industry should be promoted and recognised for its current value and significant growth potential and therefore its importance to Aotearoa New Zealand’s health system and economy.

Legislation arguments and potential unintended consequences of the Bill

The DHA and its membership wish to raise serious concerns about the potential impact and unintended consequences of the proposed Bill. In the first reading on December 14, 2022, the then Minister of Health, the Hon Andrew Little stated that the Bill will:

Provide for the timely, comprehensive, risk-proportionate regulation of medicines, medical devices, active pharmaceutical ingredients, and natural health products, and it will also include cell, gene, and tissue therapies. The bill will regulate how products are manufactured, tested, imported, promoted, supplied, and exported. The new system will align with international best practice and will be futureproofed with flexibility to ensure effective control over new technologies. (Little, 2022, para. 5)

The DHA's view is that greater regulatory oversight of software that is used on patients for purposes such as diagnosing, treating, preventing, or alleviating medical conditions, injuries and diseases, sustaining life and investigating physiological processes is necessary and that the potential risks relating to that software ought to be monitored and controlled via enhanced regulation. We support the regulation of such software (which we call "True SaMD" in this submission).

Health software is very different, however, from True SaMD. Unlike True SaMD, health software does not diagnose, treat, prevent, or alleviate medical conditions, injuries and diseases, sustain life and investigate physiological processes. Many health software products do no more than facilitate patient-doctor communications and consultations and/or assist in practice management, and generally pose no more risk of harm to the patient than any other applications used to facilitate remote interactions (e.g., Microsoft Teams) or administrative functions at a medical practice.

However, we believe that the current structure of the Bill and the broad definition of SaMD in Clause 26 where *"software that meets the definition of a therapeutic product without any associated hardware"* will inadvertently capture a significant proportion of health software suppliers that produce products of low-risk to the health and safety of New Zealanders in the health sector (New Zealand Parliament, 2023, sec. 26). We also believe that the Bill does not adequately provide a distinction between SaMD and Software in a Medical Device (SiMD).

The implementation of the legislation in its current form and potential significant unintended consequences could mean:

1. Measurable stifling of the Government's efforts to achieve digital transformation in the health sector to improve equitable health outcomes that has been identified as one of six key priorities in Te Pae Tata – Interim Health Plan 2022.
2. A significant impact on the ability of the Crown to fulfil its obligations to Te Tiriti o Waitangi through an over regulated health software industry who are working toward developing and providing culture-centric and innovative solutions to help solve the current health inequities experienced by New Zealand's Māori peoples.
3. Many health software organisations which support healthcare providers to improve health outcomes and efficiencies in New Zealand's health system could be forced out of business, thus effecting how the health system operates and New Zealand's economic growth.
4. Long lasting negative impacts on efficiency, R&D, innovation, and competition within the health software industry.

5. Poorly legislated regulation would increase the manufacturing and compliance costs of health software and subsequently increase the price of health software to health providers; the taxpayer would ultimately fund this cost.
6. Regulator overreach on low-risk health software products that have inadvertently been caught by the broad definition of SaMD would significantly decrease the productivity of the health software industry, and health services relying on developments to health software, would be measurably negatively impacted.
7. Unnecessary regulation could impact the design and update process (the software development lifecycle) which in turn could negatively impact the usability of the health software; the healthcare provider's and health consumers' user interface (UX) experience would be impacted and significantly diminished.
8. Health software entities currently contributing to New Zealand's GDP and growth as a nation could be forced to move their operations offshore reducing the economic benefit of retaining suppliers in New Zealand.

"As a small business operating from New Zealand, we have contributed to an increased awareness of our country, innovation, and leadership in value-based care. The proposed bill would significantly impact our operations and may lead to us placing our focus on other markets outside of the country." The Clinician

"The obligations and regulatory framework should be tiered to reflect these variations and potential risks associated rather than a broad-brush effect. While we encourage regulation to ensure best-practice solutions are brought to market, overweighted regulation will stifle innovation, particularly for the smaller, emerging New Zealand digital health sector. At worst case, it will push New Zealand-based providers to move operations overseas." Blaik Wilson, CEO Cemplicity

Following are some key arguments regarding the Bill the DHA and its members wish to make known. For context the DHA has sought international evidence relating to the regulation of True SaMD.

The International Medical Device Regulators Forum (IMDRF) acknowledges that:

Software is becoming increasingly important and pervasive in healthcare. Given the availability of a multitude of technology platforms (e.g., personal computers, smart phones, network servers, etc.), as well as increasing ease of access and distribution (e.g., internet, cloud), software created for medical purposes (software used to make clinical decisions) and non-medical purpose (e.g., administrative, financial) are being used in healthcare. (IMDRF SaMD Working Group, 2013, p. 4)

The World Health Organisation (WHO) stresses that "access to good quality, affordable, and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations" (WHO, 2023, para. 1). The importance of software in health and its implementation pathway should not be underestimated and must be acknowledged by the Bill's authors.

1. The current definition of SaMD is too broad and should be reconsidered.

The DHA believes that the problem the Government is trying to solve with the introduction of SaMD in the Bill is unclear. To successfully regulate True SaMD, the definition of SaMD must be articulated more clearly, and the distinction between SaMD and SiMD must be made. Currently, the Bill will apply to most individuals or companies that intend to import into, export from, manufacture or supply health software 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. 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 are likely to capture almost all companies developing or supplying any kind of health-related software in New Zealand. The DHA is particularly concerned by the breadth and ambiguity of the new therapeutic purpose introduced by section 15(j), "maintaining and promoting human health" (Little, 2022, sec. 15).

DHA submits that this definition is:

- a) Overly broad
- b) Vague and ambiguous
- c) Likely to give rise to unintended consequences, such as low risk health and wellness software being regulated as a medical device on the basis that it meets this broad definition.

As presently drafted, this definition would capture thousands of different health and wellbeing applications that are not intended to be a medical device, are low risk, and not subject to this type of regulation internationally.

The proposed definition of 'therapeutic purpose' is also much broader than the definition in the [Therapeutic Goods Act 1989 in Australia](#). As well as (j) definition above, therapeutic purpose now extends to "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 include:

- Consumer health and wellness apps
- Software within wearable devices that promotes and maintains health (by, for example, monitoring the wearer's heart rate and sending the wearer health related notifications)
- Patient apps and portals provided by medical practices
- Practice management software
- E-prescribing software.

These types of software are not generally regulated as medical devices in other jurisdictions. For example, in Australia, the following types of health software are specifically excluded from the scope of SaMD in both primary and secondary legislation:

- Consumer health and wellness products (which may be software or a combination of non-invasive hardware and software or wearables), that do not make claims about serious diseases or conditions.
- Software embedded in delivery of health services such as clinical workflow management software.

Note: The full list of the exclusions of health software for Australia can be found in the legislation recommendations section of this submission.

The DHA acknowledges that the definition of a therapeutic purpose is broad, because the Bill covers a multitude of different types of products, including but not limited to medicines, NHPs, medical devices, and SaMD. The DHA argues, however, that the Bill is trying to tackle regulation of products that are not normally grouped together e.g., medicines and NHPs with medical devices and SaMD and that consideration of this is imperative if the government does not want to tie up advancement of technology in the health sector with unnecessary burdensome regulation. It will also likely result in unintended consequences of a significant magnitude which would disrupt the supply and development of health software in New Zealand ultimately, in the end, negatively impacting economic activity, New Zealand's ability to keep up with a fast-paced changing environment, clinical practice, and, most importantly, patient outcomes.

Health software may also fall under the definition of a personalised medical device depending on its degree of personalisation and how it is produced. If health software falls within this definition, it may be subject to additional manufacturing or supply restrictions. 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 health software. The Bill sets out three different groups of personalised medical devices which may apply to health software:

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

In their submission to the Therapeutic Goods Administration (TGA) in Australia, the Medical Software Industry Association (MSIA), stated that:

As with medication, the first step in understanding any need for stronger regulation would be establishment of a process and register for reporting any perceived harm, or risk of harm, from clinical software. Only once the magnitude and types of risks that are encountered are better understood, can a rational approach to governance and mitigation be formula. (Best & Hossack, 2019, p. 5)

2. There has been a lack of adequate consultation regarding SaMD.

The DHA believes there has been inadequate consultation with the health software industry and key sector leaders, including those in government agencies, regarding SaMD. We believe that it is critical to ensure appropriate consultation has taken place and that the importance of consultation done well relating to legislation and regulation must not be underestimated.

The DHA have discovered through writing this submission that the 2018 consultation document does not record Software as a Medical Device however, it does record *“software used for a therapeutic purpose”* (Ministry of Health NZ, 2018, p. 6). SaMD does not appear in the exposure draft of the Bill except to say under section 34: *Meaning of manufacture, for medical device “Software (2) In relation to a device that is or includes software, to produce the device includes to develop the software”* (New Zealand Parliament, 2018). It is difficult to ascertain from available Ministry of Health (MOH) and government documentation whether, in fact, any meaningful consultation with the health software industry took place between 2018 and 14 December 2022, when the Bill was presented to Parliament.

The DHA and its members are very disappointed by the lack of adequate consultation with the health software industry on the proposed Bill. If we and other key stakeholders had been given the opportunity to comment on and contribute to the current version of the Bill, we could have worked with the authors on a revised and fit-for-purpose exposure draft regarding the regulation of SaMD. However, we believe moving forward that there is an opportunity for the Government to earnestly engage the DHA and the health software industry in consultation to ensure the right regulatory settings are applied to True SaMD and health software.

The DHA has been made aware through Trans-Tasman relationships that the Australian consultation between the TGA and the health software industry was open, rigorous, productive, and collaborative.

“It is acknowledged that current Medsafe legislation is dated, and this Bill is necessary. However, oversight and targeted input is required to meet the intent of the Bill. From the information available there has been very little consultation with the expertise that is directly involved in industry and the professions that this Bill will legislate.” Trevor English, Asia Pacific Healthcare Group (APHG)

3. Health software is already sufficiently regulated under existing legislation.

The DHA believes that there are already sufficient laws in place to mitigate the risks of health software under existing legislation. This is distinct from True SaMD, which the DHA agrees requires regulation via a carefully constructed Bill.

The DHA considers the key risks around health software to be:

- a) The quality of the healthcare services provided by the health practitioners using the software; and
- b) The security and privacy of patient health information and health records stored, transferred and accessed via the software.

There are already existing pieces of legislation that mitigate these risks. For example, risk a) is regulated via the Code of Health and Disability Consumer Rights (1996), and (indirectly) the Health Practitioners Competence Assurance Act (2003). Risk b) is regulated via the Privacy Act (2020), Health Information Privacy Code (2020), Health (Retention of Health Information) Regulations (1996), and the Health Information Standards Organisation (HISO) standards.

To ensure health software meets standards of safety, quality, and performance, where the software fails to perform properly, or is not fit for purpose, the Consumer Guarantees Act 1993 (CGA) provides protection by setting out various remedies. If health software is unsafe (in the unlikely event that it causes injury), under the sections 31-32 of the Fair Trading Act 1968 (FTA), the Minister can require a mandatory recall. The CGA also provides remedies for unsafe products. The DHA believes that if a safety issue were to arise, there is already sufficient regulation to deal with these issues.

In relation to advertising, the Advertising Standards Code (ASC) already regulates the advertising of therapeutic products in New Zealand. While the ASC is voluntary, it is highly respected by the advertising industry, with compliance with the Advertising Standards Authority (ASA) decisions being almost 100 percent.

In light of existing regulations, it is unlikely that the proposed regulatory changes will deliver any appreciable benefits to consumers over the current regime. To the extent there are any further benefits at all, these will be far outweighed by the negative impact of excessive regulatory processes and compliance cost.

“Clinical Decision Support (CDS) tools are where there will be an inherent grey zone in SaMD regulation. Software that applies CDS rules that have clear governance, are transparent to users and are configurable by the customer should not automatically fall into the sphere of regulation suggested by the Bill. In these situations, the software is merely acting as a conduit of information or engine to visualise the clinically governed rules. An example of this would be tools such as Health Pathways or Cortex’s dynamic documentation workflows that are entirely configured by an organisation.” Alistair Rumball-Smith, Sense Medical

4. The Bill does not adequately distinguish between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD).

The DHA believes that the Bill confuses and conflates the difference between SaMD and Software in a Medical Device (SiMD), which can be defined as “software that is part of a medical device that helps it to function in some way” (Arsene, 2020, para. 4). To qualify as True SaMD, software needs to function completely independently of existing medical devices. Any software that helps run technology like an MRI machine, an electrocardiogram (EKG), X-ray, insulin pump, or other medical devices qualify as SiMD, not as SaMD, as in other jurisdictions such as the UK and Canada.

While True SaMD does not deal with the operation of a medical device, it does frequently collaborate and work with SiMD. For instance, SaMD may examine MRI or X-ray images to look for problems, monitor EKGs and notify doctors when something is wrong, and develop a treatment plan that is carried out by an insulin pump to assist patients in controlling their diabetes. SaMD and SiMD are often mistaken since they frequently work together with medical devices. To clarify further:

If the software in question helps in any way to run a medical device, it is SiMD. Software that powers the mechanics of a medical device or processes the information that is produced by a medical device is considered SiMD. Also, software that controls the device remotely is SiMD. (Arsene, 2020, para. 10)

Therefore, the DHA believes that in relation to SaMD vs SiMD, the Bill does not provide adequate delineation and currently confuses and conflates the two categories. The DHA proposes that in order to accurately reflect the distinctions between SaMD and SiMD and to provide fit-for-purpose regulatory practices, the definition of SaMD in clause 26 of the Bill has to be clarified so as not to confuse it with SiMD.

5. Concerns over the capability and capacity of the Regulator.

The DHA has significant concerns about the future capability and capacity of the Regulator. 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. During the first reading of the Bill, 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, however a recent review of National Regulatory Authorities (NRAs) states that NRAs “globally are facing the challenge of evaluating pharmaceutical products in a speedy manner, whilst simultaneously ensuring adequate efficacy, safety, and quality of approved products. Additionally, common expectations include that the evaluation process is competent, flexible, commensurate with risk, efficient and rapid” (Yoffe et al., 2023, p. 271).

The DHA believes the Regulator needs to consider the skill set required to regulate True SaMD in comparison to the skill set required to regulate medicines and medical devices; a clear explanation and problem definition of the issue that the Regulator is trying to address, a suitable regulatory framework in place to ensure effective regulation of True SaMD, and a clearer definition of SaMD are essential components of successful SaMD regulation.

“The ability to adapt quickly to new opportunities through technology is vital. The wider the definition of SaMD the bigger the demands on the Regulator, not to mention the skills required to do the job well. Regulating medicines is not like regulating SaMD or medical devices. It is not sufficient to tack SaMD onto a Bill that is focused more on medicinal products and traditional medical devices.” Shayne Hunter, Deputy Director General Data and Digital, MOH, 2019 – 2022

Recently New Zealand saw how communications are vital in the wake of a natural disaster. Our health system needs to be resilient and requires the ability to reach isolated communities and often relies on health software to be able to not only run vital medical systems but ensure lifesaving equipment can continue to operate under pressure. Regulation that is not fit-for-purpose will only serve to stifle the advancements needed to ensure health software is resilient and can iterate quickly during change and development as we saw play out in the COVID-19 pandemic. Currently with an under resourced regulator and the strain of the technology skills shortage, the DHA believes the Regulator will be ill-equipped to manage the type of regulation posed for the wide net captured by the broad definition of SaMD in the Bill. Inadvertently caught health software suppliers needing to seek authorisation from the Regulator will only serve to slow development processes down and therefore advancements in the health sector and this will negatively affect overall healthcare services and patient health outcomes.

The DHA believes the Government needs to take into account the current capability and capacity limits of Medsafe, where there are only around 60 staff (Medicines and Healthcare Products Regulatory Agency, 2022a). The Government should compare this with the TGA in Australia which has around 1000 staff, however still struggles to approve authorisations for medical devices and SaMD in a timely manner (Therapeutic Goods Administration (TGA), 2022).

While the DHA recognises that the new Regulator will most likely increase staff numbers, we would like to point out that there is a global shortage of technology skills, not just in New Zealand. We believe the Government will find it extremely difficult to fulfil its obligations to the regulation of medical devices and SaMD with the current technology skills shortage which is predicted to remain problematic for a significant amount of time (NZTech, 2021). As well as this, current immigration settings will also mean that it may be difficult to source overseas experts in the field of SaMD to work in New Zealand (NZTech, 2022). These policy settings and barriers need to be considered when planning for the enforcement of the legislation.

In Australia, the TGA is looking to continually improve their performance relating to the regulation and authorisation of SaMD. As stated in their 2021-2022 Performance Report:

Reforms were undertaken to support emerging medical technologies such as Software as a Medical Device, while other enhancements were made to further and safeguard patients through medical device reforms. Simplified pathways and processes for industry will result in faster approval of products while maintaining our high standards of safety and efficacy. (Therapeutic Goods Administration, 2022a, p. 4)

6. The Bill does not currently support the objectives of Te Tiriti o Waitangi relating to health software.

Unique to New Zealand is Te Tiriti o Waitangi (The Treaty of Waitangi) and the Crown's obligations to provide the framework for how the health system will meet these obligations in their day-to-day work. It is recognised that Māori people have unmet health needs and overall poorer health outcomes than other New Zealanders where:

- Māori die at twice the rate as non-Māori from cardiovascular disease
- Māori tamariki have a mortality rate 1.5 times the rate for non-Māori children
- Māori are more likely to be diagnosed and die from cancer
- Māori die on average 7 years earlier than non-Māori. (Health Navigator NZ, 2022)

If New Zealand is to achieve equity and equality for the Māori people, the adoption of new and innovative technologies to help solve these inequities is vital. Te Whatu Ora – Health New Zealand have outlined in Te Pae Tata – Interim Health Plan 2022 that “to meet our obligations as Crown agents, we are building a health system that embeds Te Tiriti o Waitangi as its foundation. This means placing Te Tiriti at the forefront of thinking and providing opportunities to enact Te Tiriti principles and articles to improve health outcomes for Māori” (Te Whatu Ora - Health New Zealand, 2022, p. 7). The DHA believes this needs to be considered in the writing of the Bill.

7. The Bill does not currently harmonise with other jurisdictions relating to SaMD.

The Ministry of Health website states that the new regulation regime governed by the Bill “will align with international best practice and it will be future-proofed so that new and emerging technologies can be regulated appropriately” (Ministry of Health NZ, 2023, para. 14). However, it is hard to see how currently the SaMD definition aligns with other jurisdictions and best practices. The Bill establishes a unique regulatory framework and fails to align with international standards and practice such as those set out by the IMDRF, the U.S. Food and Drug Administration (FDA), Health Canada’s SaMD guidelines, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), or the Australian Therapeutic Goods Administration (TGA). There is no reference to risk classification (classes) or global medical device nomenclature (GMDN) in the Bill. Instead, devices are classified as either ‘use or supply restricted’.

New Zealand has a unique opportunity to become a global leader and role model for effective and agile regulation of medical devices and True SaMD, however it appears the Bill will force static regulation that is not fit-for-purpose or flexible to adapt to the rapid changes and advances in technology. We also believe it is not forward thinking and does not set a good precedent for how New Zealand should approach legislation as a whole in the future.

The FDA, who chairs the IMDRF, explains that:

Given the unique features of Software as a Medical Device that extend beyond a traditional medical device or hardware, regulators across the globe recognised the need to converge on a common framework and principles for Software as a Medical Device that enables all stakeholders, including regulators, to promote safe innovation and protect patient safety. (Food and Drug Administration, 2020, para. 4)

The UK MHRA acknowledges that the “med-tech sector is fast-paced, and our regulatory framework needs to be agile enough to respond” (Medicines & Healthcare Products Regulatory Agency, 2022, p. 6). The UK took a large-scale consultation approach to legislation change regarding SaMD as did Australia. New Zealand in contrast has sought little to no consultation with the health software industry on SaMD before adding it to the legislation and passing the first reading of the Bill in December 2022.

Another example of a lack of harmonisation with other jurisdictions is in the Bill's definition of "therapeutic purpose". The equivalent of this definition in the TGA is "therapeutic use". Australia's definition of "therapeutic use" is similar; however, as demonstrated in the comparison table below, it does not include a number of broad, ambiguous criteria that New Zealand's Bill includes (specifically, 15(g) - (l)). The DHA claims that the Bill's definition of therapeutic use is much broader than in other jurisdictions because the Bill is attempting to legislate for products that are not normally grouped together. This grouping, and thus the broad definitions, will make regulation and control difficult.

“Consistent with the approach recently taken by Australia we also recommend that 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.” Tim Packer, RUSH Digital

NZ Therapeutic Products Bill 2022	AU Therapeutic Goods Act 1989
<p>The following are therapeutic purposes:</p> <p>(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury;</p> <p>(b) influencing, inhibiting, or modifying a human physiological process;</p> <p>(c) testing the susceptibility of humans to a disease or an ailment;</p> <p>(d) influencing, controlling, or preventing human conception;</p> <p>(e) testing for human pregnancy;</p> <p>(f) investigating, replacing, modifying, or supporting part of a human's anatomy;</p> <p>(g) investigating a human physiological process;</p> <p>(h) supporting or sustaining human life;</p> <p>(i) providing vitamin, mineral, or other human nutritional supplementation;</p> <p>(j) maintaining or promoting human health;</p> <p>(k) disinfecting medical devices;</p> <p>(l) a purpose connected with a purpose referred to in paragraphs (a) to (k).</p>	<p>Therapeutic use means use in or in connection with:</p> <p>(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or</p> <p>(b) influencing, inhibiting or modifying a physiological process in persons; or</p> <p>(c) testing the susceptibility of persons to a disease or ailment; or</p> <p>(d) influencing, controlling or preventing conception in persons; or</p> <p>(e) testing for pregnancy in persons; or</p> <p>(f) the replacement or modification of parts of the anatomy in persons.</p>

Case Study – Software as a Medical Device (SaMD) reform project: Australia

In 2021-22 the Australian government refined and clarified the regulation of software based medical devices, including software that functions as a medical device in its own right (SaMD).

SaMD refers to various technologies including mobile applications, web applications, server-based systems, traditional desktop packages, cloud-based systems, or any combination of these. Since February 2021, the Australian Government engaged industry extensively to develop detailed guidance to assist many new developers who are now sponsors, as well as providing educational webinars for the sector regarding:

- The boundaries of regulation for software and excluding some products that are low risk or where there are alternative oversight mechanisms. To avoid unnecessary regulatory oversight, certain clinical decision support software was excluded, where there is no significant risk to safety, and they met certain criteria.
- New classification rules for programmed and programmable medical devices and software that diagnose, monitor, or treat diseases and conditions.
- Amendments to existing requirements in the Essential Principles from the Therapeutic Goods Act 1989 in relation to cyber security, management of data and information, and requirements relating to development, production, and maintenance to provide greater clarity.

(Australian Government & Department of Health, 2021a)

Case Study – UK SaMD Change Programme

The UK acknowledged that health software (including Artificial Intelligence (AI)) plays an essential part in health and social care. In the UK, many of these products are regulated as medical devices. In 2021, the MHRA announced the Software and AI as a Medical Device Change Programme, a programme of work to ensure regulatory requirements for software and AI are clear and patients are protected. This Programme builds upon wider reforms for medical devices as a whole detailed in the [Government response to consultation on the future regulation of medical devices in the United Kingdom](#).

Set out below is further information on each work package of the Change Programme, including deliverables to meet each set of broad objectives, and further information on how the broad Change Programme will be implemented.

The Change Programme will deliver bold steps to provide a regulatory framework that provides a high degree of protection for patients and public, but also makes sure that the UK is recognised globally as a home of responsible innovation for medical device software looking towards a global market. Broadly, to achieve this aim, we will focus on ensuring that:

- a) The requirements for software and AI as a medical device provide assurance that these devices are acceptably safe and function as intended, thereby protecting patients and public.
- b) The requirements for manufacturers are clear, supported by both clarificatory guidance and streamlined processes that work for software, as well as bolstered with the tools to demonstrate compliance, for instance, via the designation of standards.
- c) The friction is taken out of the market by working with key partners such as the National Institute for Health and Care Excellence (NICE) and NHS England to align domestically, de-duplicate, and combine requirements, ultimately providing a joined-up offer for digital health within the UK. Internationally, we will work with other regulators both bilaterally, and multilaterally through the International Medical Device Regulators Forum (IMDRF) to strengthen international convergence and consensus on software and AI products.

This programme includes eleven work packages across two workstreams. The first stream contains eight work packages to make key reforms across the software as a medical device (SaMD) lifecycle, the second stream has three work packages and considers the challenges that AI as a medical device (AIaMD) can pose over and above classically programmed software.

Objectives:

1. Ensure medical device regulations capture sufficient breadth of software to protect patients and public.
2. Ensure there is sufficient clarity yet flexibility of qualification to effectively and proportionately regulate SaMD.
3. To improve the wider regulation of digital health, through supporting and working with other regulators and processes where software does not qualify as a medical device.

(Medicines and Healthcare Products Regulatory Agency, 2022, paras 1–6)

Case Study – Canadian Guidance on Software as a Medical Device

In 2019, Health Canada issued guidance on what constituted SaMD. The guidance provides a list of important definitions, namely:

- Software as a Medical Device (SaMD) – software intended for one or more medical purposes that is not a direct part of a medical device. It is important to mention mobile apps that meet the aforementioned criteria could be defined as SaMD.
- Medical Device Data System – includes both hardware and software solutions intended to transfer, store or process medical data without making changes to it.
- Clinical Decision Support Software – intended to be used by healthcare professionals.
- Patient Decision Support Software i.e., intended to be used by users that are not professionals. It is also important to mention that the agency defines the user as a patient that is not under the supervision of a healthcare professional.

The definition used by Health Canada was initially developed by the International Medical Devices Regulators Forum (IMDRF). The concept of intended use is one of the core elements of the SaMD definition and there are several approaches to its interpretation. According to the position of Health Canada, the software intended for medical purposes is a software intended to:

- Acquire or process signal or image from the medical device, or
- Provide recommendations to healthcare professionals.

At the same time, the guidance provides a wide list of exclusions, such as:

- General administrative software used by healthcare institutions
- Software used for communications
- Wellness apps and similar software
- Software intended to manage records or information in other forms.

The software that falls within the scope of the exclusions provided above is not a SaMD. At the same time, Health Canada also provides an additional list of flexible criteria to be applied in complicated cases when the medical intended purpose is unclear. The agency also states that other factors could be evaluated when making the final decision. (RegDesk, 2019)

“Other countries have gone through the same process before New Zealand, and they have already highlighted the importance of creating clear guidelines to help companies identify when software is and is not a medical device. We found that the Australian, UK, and Canadian approaches are clearer as they include specific examples and flowcharts that are easy to follow. With these approaches, our products would be excluded from the regulation.” Mariela Boada, Best Practice

The DHA has significant concern that the Bill currently aligns itself with the European Union Medical Device Regulation (MDR) model of SaMD regulation which is proving to be problematic in administration of regulation and causing health software and medical device companies to fold or compromise the safety of their products.

The United States (U.S.) is well renowned for its technological improvement, R&D, and its capacity to realise significant economic gains through encouraging and supporting the expansion of digital and technology solutions. (Cheatham, 2022; Third Stage Consulting Group, 2023).

The aim of the FDA regarding regulation of SaMD is to:

- Enhance patient access to high quality digital medical products
- Maintain a reasonable assurance of safety and effectiveness
- Enable manufacturers to rapidly improve software products with minor changes
- Minimally burdensome. (Diamond & Food and Drug Administration, 2020, p. 6)

The DHA recommends that the Health Select Committee look to the FDA's changes to existing SaMD policies of the 21st Century Cures Act 2016 and the Federal Food, Drug, and Cosmetic Act which are realistic, flexible, and agile in their approach and where "the Food and Drug Administration (FDA) recognises the advances in software functionality, the rapid pace of innovation, and their potential benefits and risks to public health" (U.S. Food and Drug Administration, 2022a, p. 1).

In December 2019, the FDA issued guidance documents for industry and FDA staff on the regulation of health software as well as True SaMD. These guidance documents include:

- [General Wellness: Policy for Low-Risk Devices](#)
- [Mobile Medical Applications](#)
- [Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communication Devices](#)

1. The FDA recognised that health software pertaining to general wellness were low-risk and therefore did not need to be regulated. The guidance states:

That on December 13, 2019, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in section 201(h) of the FD&C Act. Section 520(o)(1)(B) of the FD&C Act, states that software that is intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" is not a device under section 201(h) of the FD&C Act. (U.S. Food and Drug Administration, 2019, p. 1)

2. The FDA issued a policy for device software functions and mobile medical applications and recognises that:

Many software functions are not medical devices (meaning such software functions do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them as devices. Some software functions may meet the definition of a

medical device, but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it does not, at this time, intend to enforce requirements under the FD&C Act). Consistent with FDA's existing oversight approach that considers functionality of the software rather than platform, FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient's safety if the device were to not function as intended. (U.S. Food and Drug Administration, 2022a, p. 2)

3. The FDA issued guidance for Medical Device Data Systems (MDDS), Medical Image Storage Devices (MISD), and Medical Image Communications Devices (MICD) stating that:

The FDA does not intend to enforce the requirements of the Federal Food, Drug, and Cosmetic Act for hardware functions that are considered to be MDDS, medical image storage devices, or medical image communication devices, provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data and results. Software functions that are solely intended to transfer, store, convert formats, or display medical device data and results, including medical images, waveforms, signals, or other clinical information, are not devices and are not subject to applicable FDA regulatory requirements. (U.S. Food and Drug Administration, 2022b, para. 1)

The DHA believes the U.S. have taken a pragmatic and functional approach to the regulation of True SaMD, recognising that software and its development has an important function within health systems, is rapidly changing, and that regulation needs to keep up with this pace of change. The DHA believes that the U.S. approach is fair and reasonable and that it should be carefully considered in relation to the Bill and applied in the context of New Zealanders' health needs.

8. The Bill could introduce significant compliance cost to health software companies.

The explanatory note to the Bill states that “therapeutic products carry both benefits and risks. A guiding principle for regulating therapeutic products is that the likely benefits should outweigh the likely risks and their regulation should be proportionate to those benefits and risks” (New Zealand Parliament, 2022, p. 2).

However, the inclusion of health software in the Bill would be extremely burdensome on health software developers. As the Bill's current definition of SaMD will inadvertently capture a magnitude of health software suppliers, unnecessary compliance cost on low-risk SaMD will come into force. To receive market authorisation under the Bill, health software providers would need to prove the safety, quality, and performance of their software. To do so, a great level of evidential and scientific documentation would be required. Achieving market authorisation will come with significant compliance costs.

“If Sysmex products do become classified as SaMD, the impact on our business is likely to be significant since our principal business area is the manufacture, import, and export of health software products. Adhering to the revised regulations will necessitate an increase to our resourcing and associated costs which will need to be passed to our customers. It may also increase the time taken to bring new and changed products to market. We request that the regulations and regulatory oversight for SaMD be considered separately from other therapeutic products covered under the bill who will have different requirements.” Kelvin Gill, Sysmex

The DHA wish to make known that the cost of unnecessary compliance could cause an increase in product prices which will be passed onto the purchaser of health software products i.e., hospitals and the health system which in turn will be absorbed by the taxpayer. This will have a negative effect on the ability to afford health software which could significantly improve clinician workflows and the lives of patients. This also does not align with the Government’s ambition in Te Pae Tata – Interim Health Plan 2022 to utilise digital technologies to help transform the health system (Te Whatu Ora - Health New Zealand, 2022).

Our members already find it hard to do business in New Zealand’s health sector. Due to the previous devolved District Health Board system, procurement of software and medical devices has been ad hoc and with different rules applying in different regions across the country. While Te Whatu Ora – Health New Zealand are reviewing current procurement practices, it could be many years before improvement and significant change will take effect. The added burden of a highly regulated health software industry and the cost recovery model of the Bill will result in increased costs to the health software industry and therefore New Zealand healthcare services with the taxpayer ultimately footing the bill.

9. The Bill has the potential to stifle innovation and productivity of health software.

Significant compliance costs mean that health software developers will be discouraged from developing innovative products. This goes against the very modernisation that the Bill seeks to promote and is likely to result in New Zealanders missing out on health software features that are available in other countries and risks stifling technological progress in New Zealand.

In the wake of Cyclone Gabrielle and other natural disasters, now more than ever, New Zealand needs to look toward sectors that can increase our Gross Domestic Product and support economic growth. The technology sector is purported to become New Zealand’s largest export sector by 2030 (NZTech, 2021). In order to fund large infrastructure projects needed for our country to repair, rebuild, and respond, as well as to grow, the Government should facilitate sectors such as the digital health and medical device industries that can contribute significant growth and economic value to New Zealand.

“We welcomed the Pae Ora legislation with its promise of health equity and delivering care closer to home using data and digital. However, we are concerned that The Therapeutic Products Bill will have the unintended consequence of making it harder for software companies to support the reforms. If innovative new software solutions become harder for clinicians to access, then it will be harder for them to implement new models of care that are meaningfully different.” Christopher Dawson, CEO Spritely

The health software industry has the potential to significantly expand from its current size, creating jobs, increasing productivity and efficiency, and improving health outcomes for minimal investment. The Return on Investment (ROI) of the technology sector is significant and should not be underestimated. The DHA is concerned that the Bill, as written, will hinder innovation and slow down our economy and productivity by tying up the health software industry with unnecessary regulations that are not in line with a risk-based approach or best practice.

Furthermore, under the current draft of the Bill, exports of SaMD will require an authorisation. SaMD exported abroad must adhere to the laws and specifications of the destination market. If New Zealand SaMD suppliers are required to apply for a New Zealand export authorisation, this could cause substantial issues with differing regulatory frameworks, further expense for New Zealand SaMD exporters, and therefore, restricted exports from New Zealand. This would ultimately have an impact on the amount of export dollars received and, consequently, New Zealand's GDP.

“As a small business operating from New Zealand, we have contributed to an increased awareness of our country, innovation, and leadership in value-based care. The Bill's requirement for SaMD products to undergo extensive pre-market approval, including approvals for changes during its lifecycle, will significantly increase the time and cost of bringing our products to market. This will negatively impact our business operations and competitiveness in both local and global markets.” The Clinician

The DHA considers that there should not be any restrictions on the export of SaMD and that it is unnecessary to expand export laws to SaMD where a destination market already requires them to be met. We believe this change to the Bill would allow New Zealand's exporters of SaMD to continue exporting without additional overheads and enable the Regulator to focus on market authorisations that are necessary for SaMD usage in New Zealand.

The OECD states that:

Governments and regulators play a major role in encouraging digital innovation and in incentivising the development of these technologies for the benefit of society. They can foster broad public and consumer interests and limit any potential unintended negative consequences of these developments by providing general rules that reflect societal values and preferences. Often, however, regulatory frameworks lack the agility to accommodate the increasing pace of technological developments. Digital technologies also challenge deeply the way governments regulate; by blurring the traditional definition of markets; challenging enforcement; and by transcending administrative boundaries domestically and internationally. (OECD, 2019, p. 1)

Professor Christian Johner from the Johner Institute in Germany explains that “the results of the MDR are that we have less products, we have less companies, we have less innovation, and patients, in some cases, are no longer treated. I believe New Zealand being a smaller and more modern country, is one of the few countries which has the opportunity to make regulation better as Europe is too big and too bureaucratic.”

10. The Bill does not consider the software development life cycle.

When considering this legislation, the Government should take into account the software development lifecycle. Typically iterative in approach, software can often experience weekly, if not daily, updates. We saw this fast iterative approach play out in the COVID-19 pandemic where the development of new and national digital solutions was vital to the effective management of the pandemic and the successful roll out of the vaccination programme. If regulation serves to hold up this process, significant burden could be placed on health software providers, resulting in a substantial negative impact on bringing products to market, stifling innovation, reducing R&D, and thus effecting access to timely updated software products and resulting in a negative impact on the health system and patient outcomes. The DHA believes that it is crucial that the Bill takes the software development lifecycle into account.



“We offer a carefully considered and well-defined approach to software product design that helps organisations innovate at speed, moving quickly from discovering different audiences’ problems (building on existing research), ideating, and validating prototypes, to a build, measure and learn product cycle. We believe this approach keeps momentum in programmes of work helping keep ahead of the innovation curve. Utilising these skills and agile ways of working we are often called up to help organisations and product companies to rapidly design, develop, and iterate on Health and Wellbeing solutions for everyday Kiwis.” Tim Packer, RUSH Digital

11. Legislation should be enabling to meet market and consumer demands.

The Bill has been written to ensure therapeutic products, medical devices, and SaMD are appropriately regulated to ensure the safety of New Zealanders and to update the out-of-date Medicines Act 1981. However, the very thing the Bill is trying to ensure, in its current form has the capacity to make worse. The DHA would surmise that New Zealand does not currently have a good track record for effective regulation e.g., the Resource Management Act (RMA) where the Ministry for the Environment states that “The RMA isn’t adequately protecting our natural environment or enabling development where it is needed. Processes take too long and cost too much, and don’t address the many new challenges facing our environment and our communities, such as the impacts of climate change” (Ministry for the Environment, 2022, para. 2). In an industry where products develop at a rapid pace, regulation needs to serve as an enabler not a disabler. Legislation should be carefully written so that it is future-proofed, and regulation can be conducted in a manner such that it can be continually adapted to the environment it finds itself in.



Professor Christian Johner from the Johner Institute in Germany who is an expert in regulatory science promotes a pathway for regulation as follows:

1. Define clear goals
2. Model the consequences of regulation
3. Try out regulation (“try fast, fail fast”) in a controlled environment
4. Collect data, learn, improve models, improve regulation.

The Regulator has the power to set rules and regulations and provide secondary legislation pertaining to the Bill. Taking the Australian approach, in New Zealand the Regulator can set exclusions for particular health software that does not qualify as True SaMD. This would be an alternative approach over changing the legislation and could evolve as the market and technology develops over time. We outline this approach further in the legislation recommendations section of this submission. We urge the Government to consider that regulation needs to be fit-for-purpose and the regulation environment adaptable and flexible to meet market and consumer demands. The DHA and its members are more than willing to assist the Government and the Regulator during a wider consultation to achieve the right regulatory framework.

12. Legislation should consider the proportionate risk of True SaMD vs health software.

The WHO recommends “regulation be proportionate to the risks particular devices pose where risk is the probability that a harmful event will occur and generate negative consequences for those exposed to it” (Hardcastle, 2022, p. 26).

While the DHA agrees that some health-related software will be classified as True SaMD, e.g., software used for the planning of radiation treatment, we argue that most health software poses little risk that a harmful event will occur and thereby compromise patient safety. As stated, the current broad definition of SaMD means that health software that poses little risk will currently be caught by the legislation and require regulation. We urge the Health Select Committee to give due consideration to the proportionate risk of True SaMD and health software, and, with consultation with the health software industry, adjust the legislation accordingly either by redefining the definition of SaMD or creating an excluded goods list via setting secondary legislation and regulations.

It must also be considered that the benefits of health software often outweigh the risks, for example:

- For health practitioners: reduced paperwork, increased collaboration with other practitioners and specialists, and efficient patient management.
- For patients: easier access to health information and records, reduced need to travel to see health practitioners (and therefore reduced costs incurred in seeing health practitioners), and more effective communication with health practitioners.
- For practices: improved business and facility management, and potentially increased patient satisfaction.

“Our software covers part of the patient journey that was previously out of reach for medical providers for logistical reasons and poses little to no risk to patients, it would be an impediment to the patients if the regulatory approval is burdensome.” Blaik Wilson, CEO Cemplicity

LEGISLATION RECOMMENDATIONS

Ultimately the DHA believes that separate legislation or secondary legislation should be developed for the regulation of True SaMD and medical devices. The DHA believes that the current Therapeutic Products Bill is problematic in that it combines the regulation of medicines, natural health products, medical devices, SaMD, and other therapeutic products which have very different risk proportions and functions across the health system. We also propose that health software is very low risk because it does not come into physical contact with patients and is not used for any purposes that are traditionally considered to be "medical".

The DHA's view is that greater regulatory oversight of software that is used on patients for purposes such as diagnosing, treating, preventing, or alleviating medical conditions, injuries and diseases, sustaining life and investigating physiological processes is necessary and that the potential risks relating to that software ought to be monitored and controlled via enhanced regulation. We support the regulation of such software (which we call "True SaMD" in this submission).

Health software is very different, however, from True SaMD. Unlike True SaMD, health software does not diagnose, treat, prevent or alleviate medical conditions, injuries and diseases, sustain life and investigate physiological processes. Many health software products do no more than facilitate patient-doctor communications and consultations and/or assist in practice management, and generally pose no more risk of harm to the patient than any other applications used to facilitate remote interactions (e.g., Microsoft Teams) or administrative functions at a medical practice.

It must be considered that the benefits of health software often outweigh the risks, for example:

- For health practitioners: reduced paperwork, increased collaboration with other practitioners and specialists, and efficient patient management.
- For patients: easier access to health information and records, reduced need to travel to see health practitioners (and therefore reduced costs incurred in seeing health practitioners), and more effective communication with health practitioners.
- For practices: improved business and facility management, and potentially increased patient satisfaction.

Along with considering the arguments outlined in the chapter above, the DHA proposes the following recommendations and amendments to the legislation to ensure the Bill is, at minimum, fit-for-purpose, can be agile in application, and evolve with a changing and fast-paced environment in relation to SaMD.

- 1. Clauses 16(3) and 19(2): In consultation with the health software industry, regulations could be made to exclude specific products (in this case, health software) from being a therapeutic product:**

Clause 16(3) contemplates regulations being made that state that a given product is not a therapeutic product. The requirements that must be met before such regulations are made are set out in clause 19(2). We believe it would be feasible and appropriate for regulations to be made under clause 19(2) to state that health software is not a therapeutic product, and those regulations should, at minimum, align to the Australian position (see below).

The DHA believes that the requirements for making regulations to exclude health software from being a therapeutic product are satisfied.

Those requirements are the ones set out in clause 19(2) i.e., that:

- (a) (i) the relevant product is adequately regulated by other means; or
- (ii) the likely risks associated with the product are sufficiently small that regulation of it is not necessary; and
- (b) in all the circumstances it is appropriate for the product not to be regulated under the Bill.

Under this approach, the current version of the Bill would not need to be amended, instead a thorough consultation with industry before the Bill comes into force could determine what software should constitute True SaMD, and what health software products should not and therefore should be excluded by way of regulations. This would also allow the Regulator ongoing flexibility if changes to the regulations are required due to the fast-paced environment of technology advancement such as the development and implementation of Artificial Intelligence (AI).

In terms of why it is appropriate for health software not to be regulated under the Bill, we note that the Australian TGA has excluded specific types of health software from the relevant definition of "Software as a Medical Device" under the Therapeutic Goods Act 1989 (Cth), and that alignment with the Australian position would be consistent with the Bill's principle that there should be co-operation with overseas regulators and, if appropriate, TGA alignment with international standards and practice (clause 4). Also, it would enhance the ease with which businesses will be able to import and export health software and True SaMD between the two countries as outlined below by DHA member Alcidion, an Australian health software company that is deployed within the New Zealand health sector.

"Alcidion would suggest that a Trans-Tasman approach to regulation would enable companies to focus their efforts on bringing more enhanced software features to our customers to support patient care, and not have to focus additional effort on ensuring compliance to two differing regulatory systems. There would be an impact on our requirements, engineering, testing, documentation, and implementation methodology should the two systems in Australia and New Zealand differ." Julia Stevens, Alcidion

Equally health software is adequately regulated by other means. The key risks around health software are:

- a) The quality of the healthcare services provided by the health practitioners using the software; and
- b) The security and privacy of patient health information and health records stored, transferred, and accessed via the software.

Risk a) is regulated via the Code of Health and Disability Consumer Rights, and (indirectly) the Health Practitioners Competence Assurance Act. Risk b) is regulated via the Privacy Act, the Health Information Privacy Code (HIPC), Health (Retention of Health Information) regulations, and HISO standards. Trade in health software itself is regulated by the Fair Trading Act and the Consumer Guarantees Act (CGA)

In relation to advertising, the Advertising Standards Code (ASC) already regulates the advertising of therapeutic products in New Zealand. While the ASC is voluntary, it is highly respected by the advertising industry, with compliance with the Advertising Standards Authority (ASA) decisions being almost 100 percent.

The TGA outlines that:

The intent of an excluded goods order is to clarify the TGA's position on the regulation of certain products. If your product is not specified in an excluded goods order you still need to consider whether it meets the definition of a medical device. If your product does not meet the legislated definition of a medical device, it is not a medical device, and is not subject to any TGA regulatory requirements. (Australian Government & Department of Health, 2021b, p. 4)

Following is the excluded goods order from the Therapeutic Goods Administration, Australia:

Excluded Goods Order for SaMD, TGA Australia

Is the software intended to be used for a medical purpose?

This will determine if the product meets the definition of a medical device (as per section 41BD of the Therapeutic Goods Act (1989):

Definition of a medical device:

- Diagnosis, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability
- Prevention of disease
- Compensation for an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Control or support of conception
- Is an accessory to a medical device (something specifically intended to be used together with a medical device to enable that device to function as intended) (Australian Government & Department of Health, 2021b, p. 5)

Software is excluded if it meets the exclusion criteria which means it is limited to performing the following functions:

Consumer health life-cycle prevention, management and follow up:

- Software intended for self-management of an existing disease or condition that is not serious (without providing specific treatment or treatment suggestions).
- Consumer health and wellness products (may be software or a combination of non-invasive hardware and software or wearables), that do not make claims about serious diseases or conditions.
- Behavioural change or coaching software intended to be used to improve general health or wellness factors (such as weight, exercise, sun exposure or dietary intake) that does not provide information to the consumer that would generally be accepted to require the interpretation of a health professional.
- PROMs (patient recorded outcome measures) and patient surveys (including those that form part of an electronic health record).
- Digital mental health tools (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software.

Enabling technology for telehealth, health care facility management:

- Communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services.
- Software intended to administer or manage health processes or facilities, rather than patient clinical use cases.
- Systems that are intended only to store or transmit patient images.
- Software intended to provide alerts or additional information to health professionals in relation to patient care. The health professional can exercise their own judgement in determining whether to action the alert or information.
- Software embedded in delivery of health services (clinical workflow management software).
- Middleware that does not control IVD instruments or medical devices and does not recommend a diagnosis or make treatment decisions.

Digitisation of paper based or other published clinical rules or data:

- Simple calculators that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.
- Electronic Patient Records (EMRs) and Electronic Health Records (EHRs) that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.

Population based analytics:

- Data analytics that are for the collection and analysis of class, group or population data that are not intended to be used for clinical use cases for individuals. (Therapeutic Goods Administration, 2022b)

Canada Software as a Medical Device Regulation Guidance

Software as a Medical Device (SaMD)

The term “Software as a Medical Device” (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

Health Canada uses the definition developed by the International Medical Device Regulators Forum (IMDRF) to help determine whether software is a medical device.

Health Canada considers that software is a medical device when:

1. It is intended to be used for one or more medical purposes as outlined in the definition of device in the Act, and
2. It performs these purposes without being part of a hardware medical device (i.e., it is not necessary for a hardware medical device to achieve its intended medical purpose).

The interpretation of the intended use is a key consideration in the determination of SaMD. The medical purposes described in the device definition of the Act are generic and can be interpreted in several ways. In the context of determining whether or not software is a medical device, Health Canada generally interprets medical purposes as follows:

- Intended to acquire, process, or analyse a medical image, or a signal from an in vitro diagnostic device or a pattern/signal from a signal acquisition system or imaging device; or
- Intended for the purpose of supporting or providing recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition.

Health Canada have the following exclusion criteria for SaMD:

1. Software that is not intended to acquire, process, or analyse a medical image or a signal from an IVDD or a pattern/signal from a signal acquisition system.
2. Software that is intended to display, analyse, or print medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies, or recommendations).
3. Software that is only intended to support a health care professional, patient, or non-healthcare professional caregiver in making decisions about prevention, diagnosis, or treatment of a disease or condition.
4. Software that is not intended to replace the clinical judgement of a health care professional to make a clinical diagnosis or treatment decision regarding an individual patient.

More information about the Canadian approach can be found [here](#). (Health Canada, 2019)

The DHA and its members in the health software industry are more than willing to collaborate with the Government in order for the Regulator to receive applicable and correct advice and therefore avoid any unintended consequences of the Bill such as:

1. An inability to achieve digital transformation in the health sector as identified by the Government in Te Pae Tata – Interim Health Plan 2022.
2. Impact on the Crown to fulfil its obligations under Te Tiriti o Waitangi.
3. Many health software organisations could be forced out of business, or to rationalise the health software products they bring into New Zealand, thus reducing the range of health software products available to health providers and consumers thus effecting how the health system operates and New Zealand’s economic growth.
4. Long lasting negative impacts on efficiency, R&D, innovation, and competition within the health software industry.
5. Increase of manufacturing and compliance costs of health software and this being passed onto health providers; the taxpayer would ultimately fund this cost.
6. Low-risk health software products being inadvertently caught by the broad definition of SaMD decreasing the productivity of the health software industry; health services who rely on developments to health software would be measurably negatively impacted.
7. Regulator overreach could impact the design and update process (the software development lifecycle) resulting in a poor user experience.
8. Health software entities currently contributing to New Zealand’s GDP and growth could be forced to move their operations offshore reducing the economic benefit of retaining health software suppliers in New Zealand.

It would also ensure gains from economic activity directly derived from the health software industry and improvements to health outcomes through health software can be realised.

3. Clause 26: Amend the definition of “Software as a Medical Device” to exclude low-risk health software products and align with international practices.

As an alternative, or in addition to option 1, the definition of SaMD in clause 26 should be amended so that it excludes low-risk health software products and aligns with international best practice. The DHA recommends that this would incorporate risk proportionate approval pathways for True SaMD, designed in alignment with internationally recognised risk classifications such as the IMDRF “Software as a Medical Device” Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF SaMD Working Group, 2014). The intention of such classification systems is to ensure that low risk products are subject to a lower level of evaluation than high risk products.

The DHA believes this approach would provide greater clarity as to what constitutes True SaMD for all parties, will help distinguish between SaMD and SiMD, and that an alignment with internationally recognised risk frameworks would better account for the majority of health software that does not pose a risk to patients.

“Our Foresite software covers part of the patient journey that poses little to no risk to patients, but it could be an impediment to providing early intervention for patients if the regulatory approval is burdensome. The obligations and regulatory framework should be tiered to reflect these variations and the potential risks associated rather than a broad-brush approach.”
Stephen Frame, SECURELY

4. Clause 44(1)(d) Manufacturing of SaMD definition is tightened around what manufacturing means in the context of SaMD.

A person “manufactures” SaMD when they do anything that is part of developing the software. 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. A remanufacturer will become the responsible manufacturer under the Bill and have associated obligations (see Market Authorisation in section 6 below). It is not clear whether the common practice of a local entity configuring overseas-standardised software for New Zealand use or for a specific customer’s use in New Zealand would cause the local entity to become the responsible manufacturer under the Bill.

The DHA suggests that clause 44(1)(d) clarifies who is intended to fall within this part of the legislation, in consideration of the iterative working processes of the software industry.

If the Health Select Committee deems this path to be appropriate, the DHA and its members would like to be a part of the consultation with the Regulator, as stated in Part 10, Clause 380 (3) on this amendment.

5. Part 2: Interpretation

a. Clause 59: Export standards

Clause 59 states that “the rules may set out standards (export standards) for therapeutic products that are exported”. The DHA argues that SaMD that is exported overseas must satisfy the regulations and requirements of the destination market, and it is the obligation of the destination market to monitor

that SaMD complies with their own regulation criteria. On this basis, it is not appropriate for export standards to apply to SaMD within the scope of the Therapeutic Products Bill.

The DHA recommends that subclause 59(1) is amended to *“The rules may set out standards (export standards) for therapeutic products (except Software as a Medical Device) that are exported”*.

We believe this change would allow New Zealand’s exporters of SaMD to continue exporting without additional overheads and enable the Regulator to focus on market authorisations that are necessary for SaMD usage in New Zealand.

6. Part 3: Dealing with therapeutic products

- a. Clause 67: Market authorisation required to import, supply, or export.

As stated in relation to Clause 59 above, the DHA strongly believes that there should be no restriction on the export of SaMD on the basis that the product is required to meet the requirements of the destination market. Accordingly, no market authorisation should be required to export SaMD.

We would recommend the following amendment to subclause 67(1)(b):

“A person must not—(b) export a medicine or medical device (except Software as a Medical Device) unless it has a market authorisation...”

7. Part 4: Market Authorisations

- a. Clause 129: Major change results in different product

According to Clause 129, a “major change” to a therapeutic product will result in a different therapeutic product that requires a new market authorisation. In the context of SaMD, “changes” are very different to changes in the context of traditional medical devices and therapeutic products such as medicines and NHPs. Additionally, the threshold of changes that “*may* have a significant impact on” is low and would be clearer if described as “*likely to* have a significant impact on”. For SaMD, a “major change” such as a user interface update, may significantly impact the overall quality and user experience of the software, but has no impact on its therapeutic application.

“Some companies use an agile product development approach where updates can be made as often as weekly. Our suggestion is to define specific rules for SaMD given the nature of software products that require regular updates (unlike regular medical devices that may have lifecycles of years). Currently, it seems that regular medical devices and SaMD are going to be treated the same way.” Mariela Boada, Best Practice

Accordingly, the DHA recommends that there are rules specifically made for SaMD regarding what constitutes a “major change”. The DHA recommends building some flexibility into the regulation to allow for the iterative process of software development and the creation of software platforms.

If the Health Select Committee deems this path to be appropriate, the DHA and its members would like to be a part of the consultation with the Regulator, as stated in Part 10, Clause 380 (3) on this amendment.

b. Clause 144: The Sponsor must notify the Regulator of certain minor changes

Any change to the therapeutic product itself or “any matter or information relating to” the product that is not classified as a “major change” (as defined in clause 129) will be a minor change. Where rules require it, minor changes must be notified to the Regulator. Minor changes for SaMD, such as updates and releases to software, are made much more frequently than for traditional therapeutic products. Moreover, the frequency of updates and minor changes in the context of SaMD reflect the industry’s ability to quickly innovate and improve their products. Given that the majority of these minor changes are unlikely to affect the product’s therapeutic purpose, a clear threshold for minor changes would enable continued innovation and quality improvement, meanwhile ensure that only changes that affect the therapeutic application of True SaMD are notified.

Accordingly, we would recommend that there are rules specifically made for True SaMD to ensure that the threshold for notification of non-major changes, is appropriate.

If the Health Select Committee deems this path to be appropriate, the DHA and its members would like to be a part of the consultation with the Regulator on these rules when they are developed, as stated in Part 10, Clause 380 (3).

8. Part 10: Administrative matters, Clause 380: Consultation

Under Part 10, Clause 380(3)

The Regulator must—

(a) consult the persons who the Regulator thinks—

(i) are likely to be substantially affected by the instrument; ... and

(b) give them an opportunity to comment (Little, 2022, pt. 10)

The DHA is aware through Trans-Tasman relationships that there was extensive consultation and engagement with the Australian health software industry resulting in successful co-design and negotiation to determine the Australian excluded goods order in relation to SaMD.

As per Part 10, Clause 380(3), before the Bill comes into force the New Zealand digital health sector believes the Regulator has an obligation to consult with it to ensure that the Bill contains an appropriate definition of “SaMD”, and that the relevant rules and/or regulations reflect an appropriate classification system for SaMD, and what health software products should be excluded from being a

therapeutic product under the Bill. As stated, the digital health industry is ready to provide advice and have an open dialogue with the Government and the Regulator on what should constitute True SaMD.

“Overall, our suggestions and recommendations to the Parliament of New Zealand is to align regulation of SaMD and other therapeutic products with those in Australia which in turn has considered regulation in Canada and the USA in their formulation. This would support the development and supply of products into New Zealand without adding significant red tape and cost to this process, which especially in the context of low-risk products is not likely to increase the safety of these products for New Zealanders.” Kathryn O’Neill, Tunstall Australasia

The DHA also proposes the following 6 key principles we believe the Bill should ensure are included:

1. The Bill must ensure risk-proportionate regulation, timely access to quality, safe, and effective SaMD and enable regulatory best practice.
2. The Bill should support equity of access to quality, safe, and effective True SaMD.
3. The Bill must support the Crown’s obligations to Te Tiriti o Waitangi and help achieve better health outcomes for Māori relating to SaMD.
4. The Regulator must be appropriately resourced and legislatively directed to fulfil its functions and exercise its powers in accordance with:
 - Principles of openness and transparency
 - A drive for continuous improvement in regulatory process and cooperation and alignment with international best practices
 - An appropriate balance between statutory independence and ministerial oversight with respect to decision-making by the Regulator
 - Fair and reasonable cost recovery.
5. The Bill should support productivity, economic activity, innovation, and be future-proofed.
6. The Bill should not impose regulatory requirements that hinder market participation or create a compliance burden that is unnecessary or inappropriate.

The following table gives a summarised view of the clauses in the Bill, and recommendations for how they might be redrafted regarding SaMD.

Clause	Issues	Recommendations
26: Software as a Medical Device.	<p>Little consultation with the health software industry was sought before SaMD was added to the Bill. This has meant that the definition of SaMD is inappropriately broad and does not align with other jurisdictions.</p> <p>The key issue is that the definition of SaMD captures low-risk software that does not come into physical (clinical) contact with patients and is not used for any purposes that are traditionally considered to be "medical" i.e., it is not used to:</p> <ul style="list-style-type: none"> • diagnose, treat, prevent, or alleviate diseases, injuries, ailments or conditions; • investigate, replace, or modify the anatomy of a person, or a physiological or pathological process or state; or • test the susceptibility of humans to a disease, ailment or condition. <p>If this low-risk health software is not excluded from the ambit of the Bill, then unnecessary and burdensome regulation will be imposed on the development and distribution of those products, and this will have significant unintended consequences for health software suppliers, New Zealand's health system, and for patient outcomes.</p>	<p>There are two alternative recommendations:</p> <ol style="list-style-type: none"> 1. 19(2): In consultation with the health software industry, the Regulator could recommend regulations that would exclude low-risk health software products from being therapeutic products. The excluded health software products should align with those excluded from the definition of "Software as a Medical Device" under the Therapeutic Goods Act 1989 (Cth), Australia. 2. Amend the definition of "Software as a Medical Device" in clause 26 to exclude low-risk health software products.
N/A	The definition of SaMD does not reflect international best practice (and this would be the case even if the recommendations set out above are adopted). Similarly, the Bill does not contain a classification system to ensure proportionate risk is applied.	Amend the definition to be more in line with international jurisdictions. Add a classification system to ensure proportionate risk is applied - [either to the definition of SaMD or in the rules or regulations that will ultimately establish the risk proportionate approval pathways].
44(1)(b): Manufacture of a medical device.	It is not clear whether the common practice of a local entity configuring overseas-standardised software for New Zealand use or for a specific customer's use in New Zealand would cause the local entity to become the responsible manufacturer under the Bill.	<p>Clause 44(1)(d) should clarify who is intended to fall within this part of the legislation, in consideration of the iterative working processes of the software industry.</p> <p>We would like to consult with the Regulator on this amendment as per Clause 380(3).</p>

Clause	Issues	Recommendations
67: Market authorisation required to import, supply, or export.	SaMD that is exported overseas must already satisfy the regulations and requirements of the destination market. Extending market authorisations to export SaMD is therefore unnecessary, and the DHA believes that there should be no restriction on the export of SaMD.	We would recommend the following amendment to subclause 67(1)(b): <i>"A person must not—(b) export a medicine or medical device (except Software as a Medical Device) unless it has a market authorisation..."</i>
129: Major change results in different product.	The provisions around what constitutes a "major" and "minor" change are unclear and the threshold for major changes is too low. In the context of SaMD, "changes" occur more frequently than in the context of traditional medical devices and therapeutic products.	We would recommend that there are Rules specifically made for SaMD regarding what constitutes a "major change". Additionally, the threshold of changes that " <i>may</i> have a significant impact on" is too low. It would be more appropriate if described as " <i>likely to</i> have a significant impact on". We would like to consult with the Regulator on these rules when they are developed as per Clause 380(3).
144: The Sponsor must notify the Regulator of certain minor changes.	The rules around what constitutes a "major" and "minor" change are unclear and the threshold for major changes is too low. In the context of SaMD, "changes" occur more frequently than in the context of traditional medical devices and therapeutic products. SaMD manufacturer's ability to innovate and upgrade technology will be hindered by the requirement for each minor change to be notified to the Regulator.	We recommend that there are Rules specifically made for SaMD to ensure that the threshold for notification of non-major changes is appropriate. We would like to consult with the Regulator on these rules when they are developed as per Clause 380(3).
Clause 380 Consultation	Consultation with the health software industry before the first reading of the Bill has not been apparent regarding SaMD, and therefore, the definition of SaMD is inappropriately broad and does not align with international best practice.	Under this Clause the Regulator must consult with the health software industry affected in earnest to determine the right level of risk proportionate regulation and/or appropriate definitions are written and applied to SaMD.

CONCLUSION

In conclusion, the DHA supports the overall intent of the Therapeutic Products Bill and recognises the importance of incorporating health software that has been appropriately classified as True SaMD into the regulatory framework. However, the DHA believes that the Bill's definition of SaMD is currently too broad, does not distinguish between SaMD and SiMD, and inadvertently captures a significant amount of health software that poses a low risk to patient safety. We believe that, in consultation with the health software industry, the definition of SaMD must be redefined, or a list of excluded products developed to prevent the unintended consequences of stifling innovation and productivity in both the health sector and the digital health industry.

While the Bill's goal is to protect patient safety, putting up regulatory barriers to health software innovation and continuous improvement could have the opposite effect by hindering manufacturers' ability to produce timely, secure health software that will allow the health system to advance and benefit from emerging technologies. Inappropriate regulation of SaMD would therefore ultimately affect health outcomes, health system gains and efficiencies, and economic activity.

Te Pae Tata - Interim Health Plan 2022 recognises digital health as one of six key priorities and acknowledges its critical role in the health sector reform by enabling timely access to healthcare services, consumer and clinician choice, and the ability to enhance population health through the gathering of health data. However, if the regulatory framework established by the Bill is not risk-proportionate and fails to take into account the quick pace of technological change in the software industry, New Zealand runs the risk of failing to realise this ambition and lagging behind other nations in the adoption of digital health technologies.

The DHA believes that New Zealand has a unique opportunity to create a global benchmark in exemplary regulation that supports the agile working processes of the software industry. This would ensure that patients can access safe and effective digital health technologies, resulting in improved health outcomes, and ensuring maximum gain from efficiencies by properly adopted technology. To achieve this, the DHA considers the Regulator must work collaboratively with the health software industry to redefine the regulatory framework and ensure that it supports innovation and continuous improvement in the health software sector while protecting patient safety. The capacity and capability of the Regulator, supported by the expertise of the digital health industry to help make decisions in relation to SaMD, will be critical for the successful implementation of this legislation.

We urge the Health Select Committee to carefully consider the DHA submission, its arguments, and suggested legislation changes. We look forward to working with the Committee and the Regulator to ensure that the final legislation or any subsequent secondary legislation supports the safe and effective use of digital health technologies in Aotearoa New Zealand's healthcare system. We believe that by doing this it will secure an extremely valuable technology sector which can serve to measurably improve the health outcomes of New Zealanders.

DHA MEMBER SUBMISSIONS



Sense Medical

Our thoughts regarding the bill almost certainly align with most members. We are for the regulation of software tools as SaMD that through their nature are likely to influence the **choice** of care a clinician makes - especially if that choice is dictated by algorithms that are coded into the software product and potentially opaque to end users. This may be through recommendation of treatment based on clinician entered data, or algorithms that selectively decide what information should be presented to end users.

Clinical Decision Support (CDS) tools are where there will be an inherent grey zone in SaMD regulation. Software that applies CDS rules that have clear governance, are transparent to users and are configurable by the customer should **not** automatically fall into the sphere of regulation suggested by the Bill. In these situations, the software is merely acting as a conduit of information or engine to visualise the clinically governed rules. An example of this would be tools such as Health Pathways or Cortex's dynamic documentation workflows that are entirely configured by an organisation.

The second point where we think there is room for improvement in the bill is the risk of stifling innovation by reducing the ability for new software that may **eventually** fall under a regulatory framework from being piloted "in the field" with appropriate clinical governance. The onus of responsibility in this situation should sit within the organisation that is piloting or involved in co-design. Regulation should only kick in at the point that software is made commercially available to the open market in New Zealand.

The final component we feel needs to be stressed in the DHA submission is the need for more granular characterisation of what SaMD is, with examples. The Australian approach here is one that we should lift and shift.

In conclusion, the move to apply regulation to SaMD is appropriate, and aligns with international best practice - however there needs to be flexibility in where and when a software product should have regulation applied. There is perhaps a role for a governance council to pre-assess solutions or else there is a risk of binary thinking based on definitions that are too all-encompassing. A bill that doesn't explicitly allow for per-case evaluation risks creating an environment that will add significant cost to businesses and herewith reduce investment in Research & Development (R&D) and ultimately decrease the impact of digital tools in improving patient care.

Alistair Rumball-Smith

Co-founder Sense Medical



Best Practice

Best Practice is a company established in 2004 and is a provider of medical software products for Australasian Specialist Practices and Allied Health Professionals, as well as General Practitioners. While in principle Best Practice supports the introduction of the Therapeutic Products Bill, we are of the view that some areas of the Bill need more clarity and improvement.

Key points/questions/concerns:

- What international standards the Therapeutic Products Bill (TPB) is aligned to?
It would be important to clarify this point, especially for companies that already have or want to place products on different markets (as our company does). The lack of harmonisation between different regulatory bodies (e.g., FDA, MHRA, EU MDR) has been recognised as an issue as they define and categorise SaMD differently. International bodies such as the International Medical Device Regulators Forum (IMDRF) and Global Medical Device Nomenclature (GMDN) are working towards improving convergence and harmonisation between different countries, but this is yet to be achieved.
- The compliance cost (market authorisations, licenses) may have negative implications to the New Zealand healthcare industry for efficiency, research, innovation, and competition. It would also result in many companies ceasing operation. Has this risk been analysed in detail, and is there any compensation plan for companies?
- Regarding the scope of market authorisation, the Bill mentions that '*major changes*' will require a new market authorisation while certain '*minor changes*' will require the vendor to notify the Regulator. About this, we have the following observations:
 - The rules around what is a '*major change*', what is a '*minor change*' and what requires notification are not clearly defined.
 - Our suggestion is to define specific rules for SaMD given the nature of software products that require regular updates (*unlike regular medical devices that may have lifecycles of years*). Currently, it seems that regular medical devices and SaMD are going to be treated the same way.
 - Some companies use an agile product development approach where updates can be made as often as weekly. How will this affect compliance vs companies that use other product development approaches like waterfall?
 - The Medical Device Coordination Group (MDCG) published [this guideline](#) about what can be considered a '*significant/major change*'. It contains a workflow specific to software that could be useful.
- The current description of Software as Medical Device (SaMD) proposed in the Therapeutic Products Bill is too broad and could have several different interpretations. Whether intended to or not, this definition may cover most of the health software developed by companies. For example, our products, whose main function is to manage medical practices' administrative tasks and store patient records, could fall under the following concepts of therapeutic purpose:
 - *Clause 15(a) - preventing, **diagnosing, monitoring**, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury;*

- *Clause 15(b) - maintaining or promoting human health.*
- While our software does not take the role of diagnosis, which remains with health professionals, it may have a support role in patient centred care by assisting in point of care decision making. Does it make our products SaMD?
- Other countries have gone through the same process before New Zealand, and they have already highlighted the importance of creating clear guidelines to help companies identify when software is and is not a medical device.
- We found that the Australian, UK, and Canadian approaches are clearer as they include specific examples and flowcharts that are easy to follow. With these approaches, our products would be excluded from the regulation.
- Also, for software that is classified as a medical device, we suggest the inclusion of detailed rules for applying regulation according to the level of risk the software may pose to users or patients. The Bill mentions that *'its intention is to provide a comprehensive, **risk-proportionate** regulation of therapeutic products'*. However, this concept is not elaborated any further.
- Australia, Canada, and the UK already have a set of rules and seem to be mostly aligned with the guidelines set up by the IMDRF.

Mariela Boada

Product Owner

Best Practice



Cemplicity

Cemplicity is a New Zealand-founded and headquartered company, established in 2013. Cemplicity is a cloud-based (SaaS) provider of Patient Reported Measures – we ask patients the right questions at the right time, surveying patients at multiple points in their healthcare journey using validated survey tools.

The survey responses are combined with information from the Electronic Health Record and reported within the Cemplicity portal to deliver insights and actions to various stakeholders and clinicians within the health system. This can range from aggregate anonymous programmes across thousands of patients to very specific symptom and side effect tracking for a very specific cohort.

For some of our deployments, we may fall under the *therapeutic purpose* definition of the bill under s15(a) as ‘monitoring’ diseases, ailments, or injuries. However, it is unclear whether this will be the case. One particular part of a product, a clinical decision support tool would likely be classified under this definition. It is not clear that it would constitute a medical device in Australia, but it would constitute SaMD under the EU and other regulations. The way the Bill is currently laid out there is uncertainty on where this and other future products will fall.

Being a software platform that allows healthcare providers to get better insight into their patients, multiple opportunities for future development may fall into the SaMD definition. That said, we play very much in the outskirts of clinical intervention – much less than say an AI-inspired tool that identifies tumours in a scanning device. Our software covers part of the patient journey that was previously out of reach for medical providers for logistical reasons and poses little to no risk to patients, it would be an impediment to the patients if the regulatory approval is burdensome.

The obligations and regulatory framework should be tiered to reflect these variations and potential risks associated rather than a broad-brush effect. While we encourage regulation to ensure best-practice solutions are brought to market, overweighted regulation will stifle innovation, particularly for the smaller, emerging New Zealand digital health sector. At worst case, it will push New Zealand-based providers to move operations overseas.

Cemplicity is not arguing for not regulating the products if they fall within the definitions, but for incorporating software-specific processes, specifically building some flexibility into the regulation to allow for the iterative process for software development and the creation of software platforms (which are different from isolated products). This would help software companies ensure that the software can continually improve to help the patients. It would also reduce the Regulator’s burden of needing to review changes that will be tracked by the software providers anyway.

Blaik Wilson
CEO Cemplicity



Rush Digital

To whom it may concern,

We strongly recommend a tighter definition of a SaMD be developed to ensure the risk of disproportionate regulation is mitigated.

Rush is a Digital Design and Technology Company. In our service to customers, we blend human-centred design, lean UX, interface design, software engineering, quality assurance and technical support to solve the wicked problems confronting people, business and society at speed and scale.

We offer a carefully considered and well-defined approach to software product design that helps organisations innovate at speed, moving quickly from discovering different audiences' problems (building on existing research), ideating and validating prototypes, to a build, measure and learn product cycle. We believe this approach keeps momentum in programmes of work helping keep ahead of the innovation curve. Utilising these skills and agile ways of working we are often called up to help organisations and product companies to rapidly design, develop, and iterate on Health and Wellbeing solutions for everyday kiwis.

After reading the Therapeutic Products Bill 2022 draft we are concerned that such solutions may be classified as a Software as a Medical Device (SaMD) and if so, believe that would introduce excessive (and unwarranted) compliance overhead, ultimately impairing their impact and effectiveness over time. It would also significantly raise the cost of such solutions.

So, while we agree with the principle of the Bill, i.e., to assure New Zealanders of the safety, quality, and performance of therapeutic products, we strongly recommend a tighter definition of a SaMD be developed to ensure the risk of disproportionate regulation is mitigated.

Consistent with the approach recently taken by Australia we also recommend that 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.

Yours sincerely,

Tim Packer
General Manager Wellington
RUSH Digital



Sysmex

Sysmex New Zealand Ltd

Laboratory Information Systems - Delphic LIS, Delphic AP, HCLAB

Clinical information system - Eclair

Sysmex may be classified as a manufacturer, importer, and exporter of software as a medical device under the Therapeutic Products Bill. However, our hope is that New Zealand will align with other international regulators (including those in Australia) who specifically exclude Laboratory Information Systems (LIS) and Work Area Managers (WAM) from classification as software as a medical device. We have provided links to supporting information provided below.

[Is my software regulated? \(Therapeutic Goods Administration, Australia\)](#)

[Examples of regulated and unregulated software \(excluded\) software based medical devices \(Therapeutic Goods Administration, Australia\)](#)

As the Bill is written, our products will be classified as software as a medical device, and may as a result affect Sysmex in the following ways:

- Regulatory overheads will increase to cover the tasks required to manufacture, import, and export our own products plus import/export third-party products. The quantum of additional costs and resources required can't be gauged until further information is provided regarding the new regulatory regime. However, any costs associated with the changes will need to be passed onto our customers who are public and private healthcare providers. As such this should be factored into the cost for New Zealand to introduce the changes.
- The cost, complexity, and lead time to obtain market authorisation for product changes may affect the frequency of updates, with changes being introduced less frequently or even omitted.
- The limited detail currently available creates uncertainty when planning new product development in the short and medium term.

The draft Bill doesn't contain the level of detail required to make an informed opinion regarding the proposals. If New Zealand regulations align with Australia, laboratory information systems and clinical information systems will not be classified as SaMD and the impact for Sysmex will be low. It will be useful for the Regulator to provide clear guidance as to which types of software products are intended to be classified as SaMD in the new regulations, and at what level. This should be done as early in the process as is practicable.

If Sysmex products do become classified as SaMD, the impact on our business is likely to be significant since our principal business area is the manufacture, import, and export of health software products. Adhering to the revised regulations will necessitate an increase to our resourcing and associated costs which will need to be passed to our customers. It may also increase the time taken to bring new and changed products to market. We request that the regulations and regulatory oversight for SaMD be considered separately from other therapeutic products covered under the bill who will have different requirements. For example, we would expect a software-specific pathway to expedite high priority updates such as bug fixes to address product quality and safety issues. The regulations will also need

clarity on what constitutes manufacturing, remanufacturing, or maintenance, and should be based on international best practice for software development.

Kelvin Gill

Quality, Regulatory & Information Security Manager
Sysmex

Medi-Map

Medi-Map has concerns regarding the current draft of the Therapeutic Products Bill in the following areas:

- Lack of clarity on the definition of Software as a Medical Device (SaMD).
 - Where the line is between a product that is or isn't SaMD.
 - If recording a result in software (from another device) meets the criteria of SaMD, paper records could also therefore be deemed in the same category.
- How software (or mobile apps) would be managed from the Google or App stores from international sources and how this would be managed, controlled, monitored. If there is an issue, how this would be managed internationally?
- There is confusion regarding the approval to export software, what this actually means and how this would be assessed in the context of a different market and jurisdiction, especially if the software isn't going to be sold or used domestically. We have concerns that the New Zealand regulator could block the ability to release software being published in overseas markets (or App/Play Stores) even though a local overseas regulator has approved this. As this would be a risk to investment in software development, New Zealand companies may move operations offshore rather than deal with a local regulator.
- The lack of local ability of the Regulator to have resources, time, and expertise to ensure timely review and approval of health software, resulting in significant delays of software releases, updating, and bug fixing. Our experience to date with Medicines Control and Medsafe is not positive and has been fraught with delays of up to a year for simple medication-based software approvals. If there was a flood of solutions for approval there would be a complete stall in health software innovation becoming available in New Zealand. The inevitable "we didn't expect this to occur" response from the Regulator would be unacceptable and result in a complete lack of confidence and trust as these issues would (and are) being highlighted at this point – well in advance of 2026. Experience to date with Medsafe and Medicine Control instil zero confidence in this not being the result.
- Cost recovery from software vendors is unclear, undefined and seems to be a mechanism to place the 'new' costs of compliance with the supplier community. In our experience, having a government agency where there are no defined cost recovery rules or values makes the process and development pricing very unclear and unattractive to proceed domestically. These new costs would immediately be passed onto the market and consumers of these software services, so price increases would be inevitable.
- Based on reading the current draft, updates and bug fixing would probably need approval by the regulator prior to release which would increase risk to patients and health professionals if updating was time critical.

The process regarding software as a medical device as per the Bill appears to be soaked in bureaucracy to the point where innovation would become stifled, responsiveness compromised and to de-risk investment, software vendors would shift development offshore. There may be a position where software vendors choose not to seek approval (especially for updates and bug fixes-which aren't defined in the Bill) and release regardless to avoid unnecessary delays due to the approval process to mitigate health and error risks.

To date, we have never seen an outcome implemented by central government that is cost effective and timely, and has resulted in improved efficiency, safety and at a lower cost – ever. We have no confidence in government enacting the Therapeutic Products Bill related to Software as a Medical Device in its current form that would give any assurance in regard to these points.

As there have been similar changes enacted overseas in other jurisdictions, we fail to understand why the writers of the Bill haven't taken learnings from these processes and outcomes (e.g., TGA in Australia and FDA in USA).

Kind Regards

Greg Garratt
CEO Medi-Map



SECURELY®

Securely

SECURELY is New Zealand-owned and operated and is a provider of medical alarms through to innovative health technologies. SECURELY has a certified Monitoring Centre based in Levin, which operates 24 hours a day, seven days a week. SECURELY is an accredited provider of medical alarms by the Ministry of Social Development. SECURELY's goal is to enable New Zealanders to live with confidence and independence while giving family and friends peace of mind that they are safe.

SECURELY offers medical alarms through to real-time activity monitoring for seniors or those at risk of falling with products like Foresite Eldercare or Essence Care@Home. These products use specialised sensors and Artificial Intelligence to provide evidence-based insights that deliver health alerts for early intervention opportunities to the user's healthcare professional. Optimally, the system will enable a person living alone to remain independent for longer, even when they may have an elevated risk of falling or disease.

SECURELY believes the wide definition of SaMD under the proposed Therapeutics Products Bill could unintentionally capture its existing products and limit new technology and products that can be introduced in the future to support New Zealand's aging population. As it is currently written, SECURELY falls under the Therapeutic purpose definition section of s15(a) as 'preventing and monitoring' diseases, ailments, or injuries. The Foresite product is a clinical support tool that would likely be classified under this definition.

Our software covers part of the patient journey that poses little to no risk to patients, but it could be an impediment to providing early intervention for patients if the regulatory approval is burdensome. The obligations and regulatory framework should be tiered to reflect these variations and the potential risks associated rather than a broad-brush approach.

SECURELY supports regulation where it ensures best-practice solutions are brought to market, however, overweighted regulation is an unintended consequence of this Bill that will stifle innovation, particularly for the smaller, emerging New Zealand digital health sector, along with lesser health outcomes for all New Zealanders.

Stephen Frame

Acting General Manager
SECURELY



Spritely

Spritely operates at an important but sometimes hard to reach intersection in the health sector. Where underserved populations, with poor access to healthcare, struggle to manage long-term chronic illnesses, which can impose a heavy burden on them, their whanau, and on society.

Our telemonitoring software provides an easy-to-use, low-cost equity of access solution that improves health outcomes by connecting patients with trained clinicians for the purpose of monitoring and coaching. It can also save nurses and patients a considerable amount of travel time, thereby increasing capacity in the health workforce and improving clinician wellbeing.

We welcomed the Pae Ora legislation with its promise of health equity and delivering care closer to home using data and digital. However, we are concerned that The Therapeutic Products Bill will have the unintended consequence of making it harder for software companies to support the reforms. If innovative new software solutions become harder for clinicians to access, then it will be harder for them to implement new models of care that are meaningfully different.

Telemonitoring software like ours is designed to improve access to care for patients and support better clinical decisions by health professionals. It helps clinicians to do their job by increasing patient contact and patient data, especially for patients where a lack of contact and a lack of data, can inhibit decision making. It doesn't change the fact that health professionals always use their own judgement to determine the optimal course of action and treatment plans.

In my opinion, it should be for these health professionals to decide what telemonitoring software is best for them and their patients. This happens now, usually following a software trial and/or a formal procurement process.

Preventing clinicians from trialling software they want, by insisting they choose from a limited set of options pre-approved by a Regulator that is unfamiliar with their requirements, will have a negative impact on clinicians, patients, and vendors.

Vendors (particularly small ones) will be reluctant to pay for the certification without a large contract, but a large contract won't be forthcoming without a certification and clinicians will be reluctant to trial uncertified software. This situation could seriously stifle innovation in the health sector at a time of unprecedented pressure for the industry.

Yours sincerely,

Christopher Dawson
CEO Spritely



Enigma

Enigma is a SME, formed in 1996, serving the public health sector with bespoke and tailored SaaS solutions. Enigma's products include providing clinical decision support to reduce the risk of patients developing cardiovascular disease, plus a number of tools used for monitoring the general mental wellbeing of people, and the physical wellbeing of people in the workplace who perform safety-critical activities. The products also include Registry products used for national key clinical performance indicator reporting. Enigma's contribution to the New Zealand health industry includes evidence generation through partnerships, e.g., with PREDICT providing the data to enable updated equations to be derived; quality improvement in CVD risk factor management; stroke prevention in AF; diabetes management, and others.

Enigma employs 11 New Zealand-based staff and relies upon New Zealand business. Enigma supports the notion of regulation specifically where it provides targeted value towards mitigating and controlling specific high-risk considerations; Enigma supports this as a tool within a risk management framework for patient safety. Enigma believes that their products would pass regulatory review however the lack of a general risk-based approach is concerning therefore the right touch implementation of any new regulation is critical.

Currently Enigma is asked by their customers to respond flexibly to their needs and to be capable of customising integration requirements and content contained within their instances. Tight and wide-spread, general regulation would overly constrain Enigma's ability to service their customers' needs. Any regulation would ideally be placed around a limited set of functional aspects of software and not against the entire instance or product as a whole. Enigma has made a substantial investment in clinical expertise in content development with rigorous processes in knowledge translation and implementation of evidence-based clinical decision rules, with explicit change management processes and pre-release testing with sentinel sites.

Enigma's products deliver innovative software solutions which, due to the current wide scope of the proposed Bill, are likely to fall under these regulations; the scope and application of these regulations will become a critical concern for their business as any excessive level of compliance will render this untenable for their business.

Enigma's aim is to assist healthcare organisations achieve their goals through utilisation of evidence-based information to improve healthcare and achieve better outcomes. As a SME, their margins are modest; they do not make excessive profit, nor inflate their pricing to contain contingency cost funding – as such, funding for such new, regulatory overheads as they might be applied to existing products or contracts, would need to fall to the customers to cover. ~70% of Enigma's turnover is sourced from publicly funded contracts which have historically had tight cost-controls applied to them, often not even allowing for CPI inflationary adjustments on any regular basis; it has been indicated that there is no provision within those government held contracts to allow for any such cost increases. Understanding and keeping compliance costs to a reasonable, and fundable, level will be critical in order for this not to have a sweeping and adverse effect on New Zealand's SME businesses which operate in this space.

Enigma's key concerns are:

1. The time and cost impact of potentially having all products and updates regulated.
2. How these new compliance costs would be met.
3. What capacity and capability the Regulator would have to adequately service the potential number of health software products which might fall under any new regulation scheme.
4. How the proposed regulations would be fairly and evenly applied to internet accessible software which might be used by New Zealanders. This could provide overseas solutions with an advantage over locally grown solutions, purely through inactive policing and enforcement of regulatory requirements against overseas entities. Software, (unlike medicines) cannot be stopped at the borders; there would be unequal protections afforded without such rigorous controls being available, which will ultimately disadvantage New Zealand businesses.

In summary, Enigma supports, in principle, the regulation of Software as a Medical Device, however, they believe that the scope of the regulation needs to be constrained, therefore applying a light touch implementation of any new regulation is critical.

Should the scope of the regulation remain as broad as it is currently, Enigma believes that the compliance costs, availability of suitably qualified regulators and the overseas advantage would have a significant detrimental impact on their ability to continue to deliver services in this industry and excessive regulation would hinder both future innovation and investment in the health system.

Chris Wiltshire
General Manager
Enigma



Alcidion

Alcidion supports the introduction of regulation for therapeutic devices where the level of regulation is proportionate to the risk posed to the patient.

We posit that different therapeutic devices will require different levels of oversight, and that some 'carve-outs' are appropriate where:

- The user is implementing existing safety and best practice protocols through the use of the software
- The clinical decision support provided by the system is explainable (e.g., rules and simple statistical models)
- There is an audit trail available to understand why recommendations were made
- Clinical decision support outputs are defined by the hospital and are 'open loop' – i.e., they require approval from a clinician to activate.

Alcidion would also suggest that a Trans-Tasman approach to regulation would enable companies to focus their efforts on bringing more enhanced software features to our customers to support patient care, and not have to focus additional effort on ensuring compliance to two differing regulatory systems. There would be an impact on our requirements, engineering, testing, documentation, and implementation methodology should the two systems in Australia and New Zealand differ.

Julia Stevens
Chief of Staff
Alcidion



Asia Pacific Healthcare Group (APHG)

Introduction APHG

25,000 New Zealanders interact with APHG pathology and laboratory service every single day. APHG employs over 2100 people, including over 75 Pathologists across Aotearoa. We employ more scientific staff than any other laboratory provider in the country. Add that to our highly capable team of technicians, phlebotomists, and couriers and we have the largest testing capacity in New Zealand. Our team of specialist pathologists, scientists, technicians, phlebotomists, couriers, and shared services personnel deliver a world-class service that together collects, analyses, and reports over 7-million patient results annually.

In Aotearoa New Zealand, 70% of all medical decisions and 100% of cancer diagnosis rely on pathology and laboratory tests. APHG's national network of pathology laboratories and supporting infrastructure provides these critical diagnostic healthcare services to our communities and hospitals.

As a proud New Zealand company, we have developed a strong geographical presence across the motu. Ultimately, it's our well-established network which makes us resilient, reliable, and good value for New Zealanders. Using our national network of 151 collection centres, 200 locally based couriers, and 2,200 staff we are able to develop regional centres of excellence, while maintaining integrated and scalable diagnostic services. Our 25 IANZ accredited laboratories give us the largest testing capacity in New Zealand.

APHG has three owners with shared values. APHG is owned by the New Zealand Super Fund, Te Pūia Tāpapa, and the Ontario Teachers' Pension Plan. Our owners share our vision for delivering an innovative, patient-centric laboratory service to the people of Aotearoa, and for generations to come.

APHG would welcome to opportunity to present a more detailed submission in-person to the Health Select Committee to further develop the impact of the issues we see raised by this proposed legislation.

The Therapeutics Products Bill

The intent of the Therapeutic Products Bill 2022 (the Bill) is 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.

The definition provided in the Bill includes all products used for the purpose of diagnosing disease, ailment, defect, or injury, and in its current for the Bill is likely to cover all products used in diagnostic testing.

The Bill introduces the concept of regulating "Software as a Medical Device" (SaMD) in New Zealand and defines SaMD as a medical device that consists only of software (e.g., breast cancer detection software). An individual or company developing, using, or supplying SaMD products, will be required to have market authorisation or other permissions before it can be used in New Zealand.

The Bill introduces a system of market authorisations, licences, permits, and standing permissions. Changing, delaying, suspending, or cancelling such permissions could have a significant impact on the interests of an individual or organisation to deliver healthcare supervised to the population of New Zealand. This system is to be overseen by a Regulator who will be responsible for issuing market authorisations, licences and permits, monitoring compliance, and enforcing compliance with the Bill.





The Regulator is proposed to be self-funding. The regulator will also be able to apply significant penalties for non-compliance.

It is possible that the future regulations and guidance may clarify some of the unclear matters in the Bill, however, we wish to make a submission to encourage clarification of the issues highlighted whether through amendments, or through future regulations and guidance.

Summary of concerns:

- **Engagement.** It is acknowledged that current Medsafe legislation is dated, and this Bill is necessary however oversight and targeted input from the relevant frontline health professionals is required to meet this intent. From the information available there has been very little consultation with the expertise that is directly involved in industry and professions that this bill will legislate. The laboratory and diagnostic sector could be significantly impacted by the Bill in its current form.
- **Innovation and agility.** The New Zealand diagnostic laboratory and scientific sector is internationally recognised for its quality and innovation. The addition of the proposed regulatory framework is likely to reduce the ability for New Zealand owned businesses to operate to current standards. New Zealand relies on innovation and translational science to enable it to fill a gap created by the lack/delay of technology and analytical systems availability in a country which is a relatively small and isolated market.
- **During the recent COVID-19 pandemic** New Zealand laboratories and their scientific staff developed and implemented world class assays and testing systems within days of accessing information and material. This was coupled with the deployment of analytical systems and software to provide access to the community which enabled New Zealand to provide a best-in-the-world response and keep the population safe. It is hard to imagine that the proposed legislation and regulatory framework would allow for this to be repeated in the same time frame and quality.
- **Cost impact:** New Zealand provides an extremely efficient diagnostic laboratory service when compared to the rest of the world. There is no ability for the sector to absorb additional costs which will result from the regulatory fees, administration costs, application time and costs, and the infrastructure required to maintain regulatory compliance.

The NZ pathology market has very different structural features to other jurisdictions

Macro drivers and funding model	Overview of addressable markets	Human pathology market	Other markets	
	 New Zealand	 Australia	 Canada (Ontario)	 U.S.
Population (mm)	5	23.5	13.5	327
Health spend per capita (NZ\$ PPP) ¹	4,958	5,533	5,531	14,282
Path. spend per capita (NZ\$)	108 ²	207	178	379
Market size	NZ\$500mm	A\$4.6bn	C\$2.05bn	US\$80bn
Pathology funding model	<ul style="list-style-type: none"> ■ Long term, predictable value contracts to private sector providers on an exclusive basis, by region ■ Hospital labs largely insourced 	<ul style="list-style-type: none"> ■ Fee-for-service via Medicare Benefits Schedule 	<ul style="list-style-type: none"> ■ Public laboratories in hospitals funded via hospital budgets ■ Private laboratories funded fee-for-service 	<ul style="list-style-type: none"> ■ Contracts with provider networks ■ Fee-for-service
Pathology market structure	<ul style="list-style-type: none"> ■ Three private providers and public hospital labs ■ Local sole provider markets 	<ul style="list-style-type: none"> ■ Three player market with two scale players having duplicated networks ■ Competition for volumes from referrers based on convenience of collection locations 	<ul style="list-style-type: none"> ■ Consolidated community lab sector with two main operators ■ Hospital labs mostly public sector operated 	<ul style="list-style-type: none"> ■ Highly competitive ■ Estimated 6,000 independent clinical labs operating in the U.S.

Source: Industry reports

¹ NZD/USD of 0.6266 as at 3 March 2020

² Reflects integrated contracts only, for comparability

- As the largest costs in the sector are staff, any additional costs are likely to impact on the quality and range of services but also on the number, type of staff employed, and New Zealand's ability to continue to attract and retain the best people.
- Software systems are extremely important to maintaining and delivering laboratory services. These include laboratory information systems (LIS), patient information systems (PMS), equipment and system interfaces, patient and system applications, logistical systems, quality and analytical systems etc. As the proposed legislation stands, the Bill would capture most/all of these systems and applications. These applications run operational systems and require regular update and change to meet changing clinical requirements.
- Specifically, this area requires clear definition as to what is included, and operational systems and access and delivery systems should be excluded.

Trevor English

Head of Strategic Business Development

APHG



The Clinician

To whom it may concern,

We, at The Clinician Limited (herein The Clinician), are writing to express our concerns regarding the proposed regulations of Software as a Medical Device (SaMD) in the New Zealand Therapeutic Products Bill 2022. Our ZEDOC solution is a digital health platform that is widely used by local and international customers, and we believe that the provisions of the Bill, as they currently stand, will have a negative impact on our business efficiency, product innovation, costs, and overall competitiveness in the market.

Firstly, the bill's broad definition of SaMD, which includes all software intended to diagnose, prevent, or treat a medical condition, will place undue burden and hindrance on innovation in the industry. The regulatory requirements for SaMD are overly prescriptive and will stifle the development of new and innovative products.

Similarly, the Bill's broad definition of 'therapeutic purpose', specifically 15(j) "maintaining or promoting human health", can be interpreted to cover a range of solutions from meditation and well-being (low risk) to Class III medical devices (high risk). Thus, it would be undue to place blanket rules against all categories of SaMD products. Specifically for The Clinician, our solution was designed to build care pathways for patients outside of the regular clinical setting. The data collected is entirely from the patient's perspective and may be used to supplement a clinician's understanding of a patient's health; however, is not used independently to diagnose, monitor, or treat a patient.

As definitions to qualify software as a medical device are still unclear and broad, we have a preference towards Australian TGA's "Is my software regulated" flow diagram (<https://www.tga.gov.au/resources/resource/guidance/my-software-regulated>). This provides a clear workflow to define whether an exemption or qualification is necessary. We encourage the Health Select Committee to consider implementing the above as part of the SaMD regulation.

Secondly, the Bill's requirement for SaMD products to undergo extensive pre-market approval, including approvals for changes during its lifecycle, will significantly increase the time and cost of bringing our products to market. Naturally, all solutions undergo regular updates for performance improvements, bug fixes, and the release of new features to meet customer needs. An additional burden will be placed on our resources to apply for approvals for new releases. We also assume that the regulatory body will be overwhelmed with applications on new software versions which will increase the processing time. This will negatively impact our business operations and competitiveness in both local and global markets.

Thirdly, we work with a number of industry leaders in and out of New Zealand. Partnerships including the integration of products and services to enable seamless healthcare performance. This provides benefits to end users by helping to reduce administrative burden, healthcare costs, and staff burnout. The Bill's current proposal makes it unclear whether integrated components of the solution also require market approval. If so, this will restrict the desire for global companies to provide their software services in New Zealand and thus, inhibit our potential to collaborate with partners.

As a small business operating from New Zealand, we have contributed to an increased awareness of our country, innovation, and leadership in value-based care. The proposed bill would significantly impact our operations and may lead to us placing our focus on other markets outside of the country.

We recommend that the Bill be amended to provide a clearer definition of SaMD that balances the need for regulation with the need for innovation. Additionally, we recommend reclassifying SaMD as a Class I or Class II medical device, which would reduce the regulatory burden and costs associated with pre-market approval.

In conclusion, we believe that the current provisions in the New Zealand Therapeutic Products Bill 2022 as they pertain to the regulation of SaMD are overly restrictive and will harm the growth and competitiveness of the digital health industry. We strongly urge the government to reconsider these provisions and make the necessary changes to promote innovation and protect the interests of industry stakeholders like The Clinician Limited.

Thank you for considering our submission.

Sincerely,
The Clinician Limited

Dr Ron Tenenbaum
CEO



Dr Koray Atalag
Co-Founder and Chief Health Informatics Officer





Healthpoint

While in principle Healthpoint believes in the regulation of therapeutic products to ensure safety and quality, we recommend a tighter definition more aligned to the Australian Government's guidance on SaMD.

Healthpoint products do not have a therapeutic purpose under clause 15, but they do provide information to readers that will enable better decisions to be made. For example, the Healthpoint Directory has been part of Aotearoa's health system for almost 20 years. Started in 2004, it is the home of almost all hauora services across Aotearoa.

The objective of the directory is to empower and inform whānau and communities, meaning:

- Improved visibility of health and social services
- Improved ability to engage confidently with health and social services
- Improved equity for whānau Māori
- Increased awareness and accessibility to services
- Reduced pressure on frontline staff
- Making health and care services more efficient to engage with.

The development and use of SaMD is a rapidly evolving area that presents unique regulatory challenges and as such the Therapeutics Products Bill 2022 includes a definition of SaMD that is generally broad and may unintentionally catch many developers and suppliers of software. The Australian Government's guidance on SaMD is designed to provide clarity and direction for developers, manufacturers and regulators in this space and is narrower and more defined in its scope.

The Australian Government's approach provides and supports:

1. **Clarity and comprehensiveness:** The guidance is clear, comprehensive and provides consistent instructions for developers as well as guidance for regulators in determining appropriate regulatory pathways.
2. **Flexibility:** The guidance is flexible enough to allow for innovation and technological advancements while maintaining appropriate regulatory oversight and does not stifle innovation.

John Williams

Chief Compliance Officer
Healthpoint

Tunstall

Tunstall

Dear Ryl,

Tunstall Healthcare would like to make the following contribution to the combined submission to Parliament regarding the Therapeutic Products Bill 2022 (Bill) by the Digital Health Association (DHA). We would also like to take the opportunity to thank the DHA for its hard work undertaken so far on advocating for our industry on this issue.

Tunstall Healthcare supplies a product affected by the proposed Bill in the form of remote patient monitoring software as well as offering medical alarm and other monitoring services and products to the community. We operate across Australia and New Zealand as well as globally and have recently experienced the changes to the regulation of Software as a Medical Device (SaMD) in Australia. Whilst in principle we support the need for increased regulation of therapeutic products and SaMD particularly we are concerned about sections of the Bill, outlined below, and their potential impacts upon supply in the New Zealand market and offer recommendations based on our experience in Australia.

1. Clarification and restriction of the application of the definition of a product as intended for use for a therapeutic purpose (Clause 15) in a similar way to that which has been applied in Australia.
 - a. Introduce categories and classes of SaMD similar to Australia and provide clear and understandable guidelines for organisations to follow to ensure they can comply. Many suppliers are small and medium size enterprises and the cost of accessing specialist legal advice to determine a product's eligibility or not for regulation can be prohibitive to growth and innovation. On initial introduction of the increased regulation in Australia many of these guidelines were not available, and we had to rely on our own interpretation of specific words in definitions and hope that their interpretation was justified. Many months after the regulations were enacted clear and understandable guidelines for interpretation were released, and our organisation was able to feel confident in their interpretation of the legislation.
 - b. Consider the impact of the current definition upon application and how it would likely restrict supply and availability of products in New Zealand without gains in safety for a New Zealand consumer. For example, Australian regulation distinguishes between software intended for general and health professional only consumption as well as software that simply provides a digital version of information/data that could be obtained/confirmed another way and/or conforms to widely accepted evidence-based guidelines and recommendations as opposed to software that provided information or interpretations/diagnoses that could not be obtained in any other way.
2. Part 4 of the Bill (including Clauses 119- 121) focus upon the process to achieve market authorisation and is quite broad in its statement regarding the assessment of products proposed to market. For example, software used to monitor or to aid a clinician in managing a person's condition would likely be defined as a therapeutic purpose thus requiring regulation and proof of safety, quality, and performance which can be very hard to identify and prove in all

its nuances. Therefore, we would recommend providing clear processes for assessment of products in line with their risk categorisation and intended uses.

Overall, our suggestions and recommendations to the Parliament of New Zealand is to align regulation of SaMD and other therapeutic products with those in Australia which in turn has considered regulation in Canada and the USA in their formulation. This would support the development and supply of products into New Zealand without adding significant red tape and cost to this process, which especially in the context of low-risk products is not likely to increase the safety of these products for New Zealanders.

Kind regards,

Kathryn O'Neill

Clinical Services Manager

Tunstall Australasia



Manage My Health

The Therapeutics Products Bill: a perspective from Manage My Health Global Ltd

Manage My Health (MMH) is personal health software that gives individuals electronic access to their personal health records held by their doctor and other healthcare providers, and therefore accurate information about their health status. This enables people to understand and manage their own health and well-being, together with their doctor and other healthcare providers. Our objective is to assist people to improve their own and their families' health literacy and care planning.

MMH was created and is headquartered in Auckland, New Zealand. We currently have 1.5 million people in New Zealand registered to use our software, and a growing international footprint.

MMH is a digital platform hosted 'in the cloud', with servers based in New Zealand. We provide MMH as 'software as a service' (SaaS).

In terms of the proposed Therapeutic Products Bill, the therapeutic purpose defined for MMH would likely be interpreted under Subpart 2, section 15(j), since we are a maintaining or promoting human health through information and service co-ordination.

We co-ordinate the monitoring, treatment and prevention activities for a disease, ailment, defect, or injury, and can influence or investigate a human physiological process via connections with wearable technologies to our platform. We are also increasing fine-tuning smarter care co-ordination through the exploratory use of Artificial Intelligence (AI).

MMH is used by medical practices to co-ordinate repeat prescription requests, support video consultations, host shared care plans, and co-ordinate patient journeys. Each is potentially a standalone feature of the platform, and our perception is that under this Bill, each would be considered to be a different therapeutic product and therefore be subject to individual regulation as well as annual levies or fees.

We also manage separate software products and services that are connected to the health information recording systems on our platform. These include 'Beating the Blues', an internationally certified behavioural therapy tool. Under the Bill, it could be interpreted that each feature of the portal may fall into a separate therapeutic product category, and therefore may require market authorisation, export controls, reporting of variation of market authorisation for every upgrade (to avoid the tampering clauses), and establish intensive surveillance and response systems. We would also be limited on what can be used for marketing and engagement purposes under potential misrepresentation of therapeutic products and advertisements.

There is also significant scope for difficulty in terms of market authorisation requirements, since we intend to import new enhanced technologies that emerge in other countries including from our own software development teams in those countries, to support the platform in New Zealand.

MMH also operates in Australia, India, and several other countries and is compliant with their registration and regulatory systems and processes.

These are major considerations, the implications of which for our products and services we need to understand.

Ross Tanner

Director

Manage My Health

Samuel Wong

General Manager – Product Management

Manage My Health



Just a Thought

As the developer of digital CBT courses, we appreciate that a medical approach to regulation is clearly needed for many devices to ensure patient and practitioner safety, but it does not necessarily accommodate the standard software industry approach to development, maintenance, and innovation. As an evidence-based product, our online CBT courses have undergone multiple randomised control trials, proving their safety and effectiveness.

The Bill's definition of Software as a Medical Device (SaMD) is broad and may unintentionally include many developers and suppliers of health software. As such, we would like to see clarification on the Bill's proposed definition of 'therapeutic purpose', as well as a clearer definition for SaMD. We also believe that aligning the application of SaMD with the Australian implementation could be beneficial, as it would provide more certainty for the digital health industry in Aotearoa.

The Bill also states that the original market authorisation will cover subsequent minor changes to a product, but major changes will require new market authorisation. Given the frequency of modifications in software compared to traditional products, it is unclear what kind of changes would require notification, and whether bug fixes, enhancements, or new features would fall within this category.

In summary, while we support the Bill's goal of ensuring patient and practitioner safety, it is our hope that the Bill can be amended to strike a balance between safety and practicality, and to provide the digital health industry with the clarity and certainty it needs to continue growing and improving the lives of people in Aotearoa.

Charlie David

General Manager

Just a Thought

REFERENCES

Arsene, C. (2020). *SaMD vs SiMD: What's the difference?*

<https://www.healthtechzone.com/topics/healthcare/articles/2020/06/29/445836-samd-vs-simd-whats-difference.htm>

Australian Government, & Department of Health. (2021a). *Regulatory changes for software based medical devices*. <https://www.tga.gov.au/sites/default/files/regulatory-changes-software-based-medical-devices.pdf>

Australian Government, & Department of Health. (2021b). *Examples of regulated and unregulated software (excluded) software based medical devices*.
<https://www.tga.gov.au/sites/default/files/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices.pdf>

Best, R., & Hossack, E. (2019). *MSIA submission to the TGA: In respect of software as a medical device*.
[https://www.msia.com.au/public/137/files/Submissions%20and%20Letters/MSIA_Submission_TGA-EH-1\(1\).pdf](https://www.msia.com.au/public/137/files/Submissions%20and%20Letters/MSIA_Submission_TGA-EH-1(1).pdf)

Cheatham, K. (2022, July 4). *How technology has changed America*. <https://www.thirdstageconsulting.com/how-technology-has-changed-america/>

Diamond, M., & Food and Drug Administration. (2020, February). *Proposed regulatory framework for modifications to Artificial Intelligence/Machine Learning (AI/ML)—Based software as a medical device*. <https://www.fda.gov/media/135713/download>

Food and Drug Administration. (2020, September 9). *Software as a Medical Device (SaMD)*. FDA; FDA.
<https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd>

- Hardcastle, L. (2022). *Left to their own devices? The future of medical device regulation in Aotearoa/New Zealand* [Thesis, Open Access Te Herenga Waka-Victoria University of Wellington].
<https://doi.org/10.26686/wgtn.21220343>
- Health Canada. (2019). *Guidance document: Software as a Medical Device definition and classification*.
<https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document/software-medical-device-guidance-document.pdf>
- Health Navigator NZ. (2022, December 26). *Māori health overview*. Health Navigator New Zealand.
<https://www.healthnavigator.org.nz/clinicians/m/māori-health-overview/>
- IMDRF SaMD Working Group. (2013). *Software as a Medical Device (SaMD): Key definitions*.
- IMDRF SaMD Working Group. (2014). *'Software as a Medical Device': Possible framework for risk categorization and corresponding considerations*.
- Little, A. (2022, December 14). *Therapeutic Products Bill—First reading*.
https://www.parliament.nz/en/pb/hansard-debates/rhr/combined/HansDeb_20221213_20221214_20
- Medicines & Healthcare Products Regulatory Agency. (2022). *Government response to consultation on the future regulation of medical devices in the United Kingdom*.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf
- Medicines and Healthcare Products Regulatory Agency. (2022, October 17). *Software and AI as a Medical Device change programme—Roadmap*. GOV.UK.
<https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap>

Ministry for the Environment. (2022, November 15). *Why we need resource management reform*.

Ministry for the Environment. <https://environment.govt.nz/what-government-is-doing/areas-of-work/rma/resource-management-system-reform/why-we-need-resource-management-reform/>

Ministry of Health NZ. (2018). *Therapeutic Products Regulatory Scheme consultation*. Ministry of Health NZ. <https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation>

Ministry of Health NZ. (2023). *Therapeutic products regulatory regime*. Ministry of Health NZ.

<https://www.health.govt.nz/our-work/regulation-health-and-disability-system/therapeutic-products-regulatory-regime>

New Zealand Parliament. (2018). *Therapeutic Products Bill—Draft for consultation*.

<https://www.pco.govt.nz/assets/Uploads/legislative-documents/consultation-draft-Therapeutic-Products-Bill.html>

New Zealand Parliament. (2022). *Therapeutic Products Bill explanatory note*.

<https://www.beehive.govt.nz/sites/default/files/2022-11/Therapeutic%20Products%20Bill.pdf>

New Zealand Parliament. (2023, February 21). *Therapeutic Products Bill*.

https://www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_130084/tab/video

NZTech. (2021, July 4). New Zealand facing a digital skills crisis. *NZTech*.

<https://nztech.org.nz/2021/07/05/new-zealand-facing-a-digital-skills-crisis/>

NZTech. (2022, May 11). Further recognition tech skills critical for New Zealand. *NZTech*.

<https://nztech.org.nz/2022/05/12/further-recognition-tech-skills-critical-for-new-zealand/>

OECD. (2019). *Regulatory effectiveness in the era of digitalisation*. <https://www.oecd.org/gov/regulatory-policy/Regulatory-effectiveness-in-the-era-of-digitalisation.pdf>

RegDesk. (2019, December 24). Health Canada issues guidance on SaMD. *RegDesk*.

<https://www.regdesk.co/health-canada-issues-guidance-on-samd/>

Te Whatu Ora - Health New Zealand. (2022). *Te Pae Tata Interim New Zealand Health Plan 2022*.

<https://www.tewhatauora.govt.nz/publications/te-pae-tata-interim-new-zealand-health-plan-2022/>

Technology Investment Network, & Consortium for Medical Device Technologies. (2020). *New Zealand HealthTech insights report 2020*. <https://tin100.com/product/new-zealand-healthtech-insights-report-2020/>

Technology Investment Network, & Consortium for Medical Device Technologies. (2022). *New Zealand HealthTech insights report 2022*. <https://tin100.com/product/2022-healthtech-report/>

Therapeutic Goods Administration. (2022a). *Regulator performance report 2021-2022*.

<https://www.tga.gov.au/sites/default/files/2022-11/regulator-performance-report-2021-22.pdf>

Therapeutic Goods Administration. (2022b, June 21). *Excluded goods orders, determinations and specifications* [Text]. Therapeutic Goods Administration (TGA); Therapeutic Goods Administration (TGA). <https://www.tga.gov.au/excluded-goods-orders-determinations-and-specifications>

Third Stage Consulting Group. (2023). *The 2023 digital transformation report*.

https://4559297.fs1.hubspotusercontent-na1.net/hubfs/4559297/2023_Digital_Transformation_Report_v4-111522-1.pdf?_hstc=21868836.c243592f73d7f60aeee07da2ddaeb6cd.1677288750365.1677288750365.1677288750365.1&_hssc=21868836.1.1677288750366&_hsfp=3340026030

U.S. Food and Drug Administration. (2019). *General wellness: Policy for low risk devices—Guidance for industry and Food and Drug Administration staff*. <https://www.fda.gov/media/90652/download>

U.S. Food and Drug Administration. (2022a). *Policy for device software functions and mobile medical applications*. <https://www.fda.gov/media/80958/download>

U.S. Food and Drug Administration. (2022b, September 27). *Medical device data systems, medical image storage devices, and medical image communications devices*. U.S. Food and Drug

Administration; FDA. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices>

WHO. (2023). *Medical devices*. <https://www.who.int/health-topics/medical-devices>

Yoffe, A., Liu, J., Smith, G., & Chisholm, O. (2023). Regulatory reform outcomes and accelerated regulatory pathways for new prescription medicines in Australia. *Therapeutic Innovation & Regulatory Science*, 5(2), 271–286. <https://doi.org/10.1007/s43441-022-00465-2>