

Submission on the Repeal of the Therapeutic Products Act

DIGITAL HEALTH ASSOCIATION NZ INCORPORATED

29 JULY 2024



DHA

Digital Health Association

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Introduction to the DHA - Who We Are The Digital Health Association (DHA), with over 200 member organisations, is the peak industry and advocacy body for the digital health sector in Aotearoa New Zealand. We provide a representative, agnostic, and independent viewpoint, supporting engagement across the health and digital health sector and various portfolios and programmes across government and in the Data and Digital Directorate of Health New Zealand | Te Whatu Ora.

Our Vision

To support and grow a thriving and vibrant digital health ecosystem.

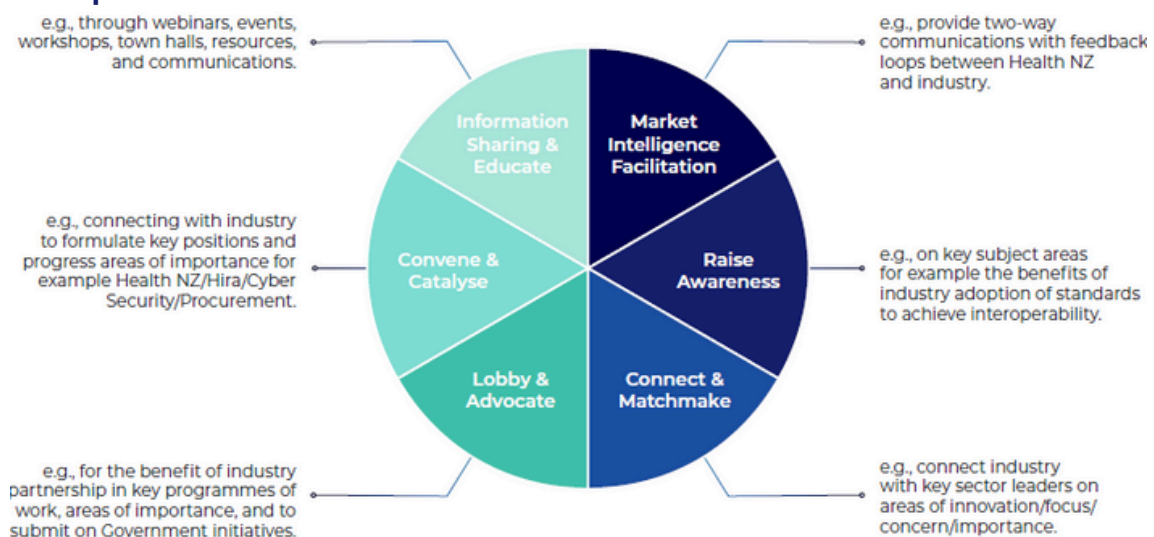
Our Purpose

To create an environment where the DHA's informed and influential voice actively supports members and advocates for the growth and use of digital health technologies in New Zealand and globally.

Our Diverse Membership

Our members include digital health companies, health providers, not-for-profits, local and central government agencies, and various consulting, insurance, and legal practices. This diversity allows us to gather a wide range of insights on key issues and collaborate effectively on digital health initiatives.

Our Purpose and Function



The Digital Health Association's Submission on the Repeal of the Therapeutic Products Act

Thank you for the opportunity to make this submission on the repeal of The Therapeutic Products Act 2023. The [Digital Health Association](https://www.dha.org.nz) (DHA) supports the Bill to repeal the Act.

Background:

New Zealand's health information and digital health systems are governed by a complex web of laws and regulations that are fragmented, siloed, and often create barriers to the efficient flow of health information.

Together, the eight Acts and sets of regulations that pertain to digital health can result in:

- **Legal uncertainty:** The ambiguity stemming from poorly defined legislation deters investment and innovation.
- **Data privacy and security risks:** Due to overly burdensome privacy laws and regulations.
- **Compliance challenges:** Legislation that does not align with international standards can lead to conflicting rules and requirements in different jurisdictions, creating compliance challenges.
- **Patient safety concerns:** Resulting from inaccurate or incomplete regulations.
- **Inequitable access:** Regulatory barriers can limit the adoption of digital health solutions.
- **Stifled innovation:** Stemming from unclear or overly restrictive regulations.
- **Interoperability challenges:** The goal of seamless, patient-centred care and the efficient exchange of health information can fall victim to legislation and regulation.
- **Regulatory gaps:** These can leave new technologies unregulated.
- **Delayed benefits:** Ineffective legislation/regulation can hinder the implementation of digital health solutions, delaying benefits for patients and the health system, and waste resources for government agencies, businesses, and healthcare providers.

The Therapeutic Products Act 2023:

The Therapeutic Products Act in its current form 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). The DHA submitted an extensive document in March 2023 to the Health Select Committee on Software as a Medical Device (SaMD) in the Therapeutic Products Bill and presented orally to the Committee. We are very pleased to be able to submit again in relation to the repeal of the Act.

The DHA and our members supported the overall intent of the original Bill—to ensure therapeutic product legislation is up to date and fit-for-purpose, and to provide a mechanism to keep New Zealanders safe from harm relating to therapeutic products. 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. The DHA acknowledged that some health software will need to be regulated as SaMD, however, we remain concerned about the broad definition of SaMD in the Act and that the current definition could inadvertently capture low-risk health software that should not be subject to such stringent regulation.

The DHA believes that the current 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 Act 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 Act.

We believe that the current structure of the Act 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).

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

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 in the [Government Policy Statement 2024 - 2027](#).
2. 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.

3. Long lasting negative impacts on efficiency, R&D, innovation, and competition within the health software industry.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.

Currently, the Act will still 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 current Act 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 remains too broad and should be reconsidered.
2. Health software is already sufficiently regulated under existing legislation.
3. Concerns over the capability and capacity of a new Regulator.
4. The Act does not currently support the objectives of Te Tiriti o Waitangi in relation to health software.
5. The Act does not currently harmonise with other jurisdictions relating to SaMD.
6. The Act could introduce significant compliance cost to health software companies.
7. The Act has the potential to stifle innovation and productivity of health software suppliers.
8. The Act does not consider the software development life cycle.
9. Legislation should be enabling to meet market and consumer demands.
10. Legislation should consider the proportionate risk of True SaMD vs health software.

We also believe the following six broader principles were not addressed in the Act:

1. The Act must ensure risk-proportionate regulation, timely access to quality, safe, and effective SaMD and enable regulatory best practice.
2. The Act should support equity of access to quality, safe, and effective True SaMD.
3. The Act 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 Act should support productivity, economic activity, innovation, and be future-proofed.
6. The Act should not impose regulatory requirements that hinder market participation or create a compliance burden that is unnecessary or inappropriate.

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. 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 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 Act.

We believe the Act as legislated could have the potential to stifle an extremely valuable and growing industry in Aotearoa New Zealand and impact health services and patients negatively, which is why we support the repeal in order to have an opportunity to revisit any concerns.

Therefore, we look forward to working with the Government to take advantage of this unique opportunity to create modern legislation that is adaptable, flexible, agile, and forward-thinking and does not impose overly burdensome regulation on health software or True SaMD.

The DHA welcomes further discussion on the design of the new legislation.

Ngā mihi nui,

Ryl Jensen

CEO

Digital Health Association