CONSUMER ADVOCACY ALLIANCE
Experts by Experience

Submission on the Therapeutic Products Bill

5 March 2023

1. The Consumer Advocacy Alliance

The Consumer Advocacy Alliance is an independent consumer alliance that ensures scrutiny of the health system at all levels — including all government, public and private health entities — for the benefit of all New Zealanders, to protect people from harm and to ensure quality consumer-focused health care and services.

Being independent allows us to be intentionally consumer-focused; independence enables us to evaluate health issues objectively and work constructively with the sector to find solutions.

We are a collective of experienced health care advocates who share a common passion for creating positive, effective and lasting change. Our founders have a common standpoint; that health care, as it is now, is not working; that the experience of New Zealanders in the health system is not what it should be. By working together and pooling our experience we identify areas and opportunities where we can facilitate change within the health system and ensure that our voice, the consumer voice, is heard.

2. General Support for the Therapeutic Products Bill

We support the need for the Therapeutic Products Bill (TPB) to replace the Medicines Act 1981 as it is no longer fit for purpose. We strongly support the purpose of the TPB, to protect, promote, and improve the health of all New Zealanders; the health, well-being and safety of New Zealanders is of paramount importance.

We also strongly support the Bill's purpose to ensure acceptable safety, quality, and efficacy or performance of therapeutic products, and that therapeutic products must be regulated across their lifecycle. We agree that regulation should support choice of, and equity of access to, therapeutic products.

We support the establishment of a new Therapeutic Products Regulator as long as it is truly independent, its main priority is patient safety, and it is not market-focussed favouring corporates within the medico-pharmaceutical industrial complex.

3. Consumers Rights and Consumer Representation

We strongly believe that ALL consumers have an inalienable right to be involved at ALL levels of the health system, in line with the Pae Ora (Healthy Futures) Act 2022.

The Code of Expectations for health entities' engagement with consumers and whānau[1] was a requirement under the Pae Ora (Healthy Futures) Act 2022 (Section 59 and Section 60). We strongly believe that ALL consumers have an inalienable right to be involved at ALL levels of the health system, in line with the Pae Ora (Healthy Futures) Act 2022, and promises made by the New Zealand Government that the "new" health system would be a people-centred one.

We expect that the Therapeutic Products Regulator will, like other health entities, be a signatory to the Code of Expectations and "act in accordance with the code approved under section 59 when engaging with consumers and whānau" and "report annually on how it has given effect to the code".[2]

1 https://www.hqsc.govt.nz/resources/resource-library/code-of-expectations-for-health-entities-engagement-with-consumers-and-whanau/

2 As per Section 60 in the Pae Ora (Healthy Futures) Act 2022.

We are disappointed that this is not explicitly set out in the TPB and submit that the proposed legislation MUST be amended to ensure that the Therapeutic Products Regulator complies with both the letter and spirit of the Pae Ora (Healthy Futures) Act 2022. Additionally, any secondary legislation that empowers the Therapeutic Products Regulator MUST also include the requirement that the Regulator act in accordance with the Code of Expectations.

The TPB also makes no reference to the Code of Health and Disability Services Consumers' Rights with regard to the rights of consumers; this must be rectified. We fail to see how there can be legislation that regulates the provision of therapeutic products to consumers without acknowledging the Code of Health and Disability Services Consumers' Rights, particularly when it comes to issues such as the provision of information about therapeutic products to enable consumers to make informed decisions, and participation in clinical trials.

The wording of Section 380 Consultation is concerning because it relies on the Regulator determining who will be affected by any regulations rather than taking the standpoint that ALL New Zealanders may be affected and are entitled to be consulted. Limiting consultation is contradictory to the intent of the Pae Ora (Healthy Futures) Act 2022. It is not consumer-centred to have any Government agency or health entity, including the new Regulator, decide who should or should not be consulted. Ideally consumers should have a "seat at the table" throughout, to be involved in developing policy, legislation, rules and regulations to ensure that consumer safety is paramount.

Advisory committees (Section 347) and review panels (Section 358) MUST include consumer representatives with lived experience, including multiple consumers on any given advisory committee and/or at different times depending on the products that the Regulator requires advice on. Consumer representation on advisory committees would comply with the World Health Organisation's "Global Patient Safety Action Plan 2021-2030", the Code of Expectations for Health Entities' Engagement with Consumers and Whānau, and the Pae Ora (Healthy Futures) Act 2022.

We strongly agree with a regular review of the Act (Section 382) and believe that consumer engagement is vital in these reviews. The new Regulator MUST be required to engage with and consult with consumers where any consultation is required, including in reviews of the Act, the strategy and recovery of costs. Consumer groups/key consumer stakeholders MUST be invited to participate in the review and to provide feedback. This also applies to any other reviews, such as the Regulatory strategy for performance of functions and exercise of powers (Section 334).

4. The New Therapeutic Products Regulator:

The Consumer Advocacy Alliance looks forward to a truly independent Therapeutic Products Regulator, that is adequately resourced (financially and in terms of staffing and expertise), and supported by the appropriate legislative power act in the best interests of consumers, and on cases of patient harm. The independence of the Regulator from the MoH and DGoH is vital. When this role is established, policy and legislation developed should reflect this independence.

Regulation of implantable medical devices and certain procedures (e.g. surgical mesh, endometrial ablation) has been consistently woeful and inept, leading to significantly greater harm caused to consumers over many years, than would have been the case if medical devices had been properly regulated. We expect that the new Regulator will address the past inadequacies, be accountable for ensuring products released onto the market if accepted under fast tracking processes such as the FDA 510 (K) clearance, are heavily scrutinised.

We believe that the Regulator as an independent health entity, should be required to present an annual report to Parliament and to the New Zealand public/consumers, as is the case with other such agencies, such as the Health and Disability Commissioner. The Regulator must clearly detail improvements that have been made and will be made to harm reporting processes, and must be transparent around potential safety concerns. Safety Communications, Alert communications, withdrawals and recall of products must be available to the public, accessible and easily visible.

The sharing of information (Section 343), MUST include sharing of information with other health and related entities such as ACC, HQSC, and the HDC, including adverse event reporting and notifications of harm. In addition, the Regulator must have the power, ability and legal requirement to respond to notifications of patient harm, and

to suspend or ban the use of harmful products. Any product causing harm below a threshold for suspension or banning, must attract a "black box" warning that the Regulator must have the power to enforce.

Regarding Section 358 (Regulator to convene review panel), it would be a conflict of interest for the regulator to appoint the panel reviewing its own decisions. As an alternative, the Health and Disability Commissioner, being concerned with the protection of consumer rights, and having the requisite knowledge in the field could appoint the review panel, or some other independent review body should be established.

The Regulator must take care regarding reliance on overseas regulators in making decisions on product authorisations, particularly regarding implantable medical devices that are grossly under-regulated globally.

The Regulator must also share other information with relevant health entities in New Zealand, such as ACC, HQSC and the HDC, regarding harm from therapeutic products and treatment injury, so there is a comprehensive understanding of the level patient harm that occurs.

5. Patient/Consumer Safety

The Consumer Advocacy Alliance believes that patient/consumer safety is of paramount importance in any legislation or regulatory regime that controls therapeutic products; all other considerations are secondary.

We understand that all therapeutic products carry risks and benefits. There is repeated statement in the TPB that the "likely benefits should outweigh the likely risks". This is a critical principle and how benefit and risk is balanced is crucial to whether or not the Bill protects consumers. However, a simple calculation that "benefits outweigh risks" is a low threshold and risks permitting products that are not harmful 51% of the time. Using such an inadequate measure, results in situations like the surgical mesh issue, where a therapeutic product could cause catastrophic harm for thousands of people, yet still be evaluated as having benefits, even with a lack of data or evidence of this.

We strongly support this provision for therapeutic products to be regulated across their lifecycle (Section 3). This is particularly important for implantable devices and medicines for which there is limited pre-licensure safety data, especially long-term follow-up, and that may cause harm many years after implantation or prescribing (e.g. breast implants, surgical mesh, Cox 2 inhibitors, drugs like Primados and DES, among many others).

We want to see extremely robust regulations and enforcement around surveillance and monitoring – that required of the sponsor and also the independent Regulator's own surveillance and monitoring. There must be considerable emphasis on the Regulator's ability to respond swiftly and decisively on reports of harm, and a focus on taking a precautionary approach to ensure the safety of consumers.

A critical instrument in the surveillance and monitoring is to include a medical device register. Providing patients with relevant information about the devices they have implanted is essential. The establishment of a new system which enables implantable products to be more easily identified, and where patients can be tracked is crucial.

While it is important to hold sponsors of therapeutic products accountable and ensure that they foot the bill for monitoring and collection of PROMs (patient reported outcome measures) and reports of harm, it is vital that we also have an independent system. In addition, it must not be a passive system in which it is often up to the harmed consumer to report adverse events/effects. It must be a requirement of practitioners to report adverse effects and harm when patients report it.

Adverse event reporting by practitioners must be made mandatory

All too often practitioners dismiss patient concerns and symptoms of an adverse effect or symptom of harm, because they cannot find any other record of such symptoms. This becomes a vicious cycle of patients not having harm and injury taken seriously, while escalating numbers of patients suffer. We have utterly inadequate systems for the reporting of harm and a non-existent, or lack-lustre and slow response to reports of serious harm, that typically relies on injured consumers having to take on the role of red flag-raiser, whistle-blower, educator and lobbyist, to prevent further harm to more New Zealanders.

6. Regulation of Implantable Medical Devices

Stringent regulation of implantable medical devices is critical!

International research has found that globally, implantable medical device regulation is unfit to protect patients from harm. In New Zealand, like many other countries grossly inadequate regulation of medical devices has led to catastrophic levels of harm being inflicted upon health consumers.

The *Implant Files* investigation was the first-ever global examination of the medical device industry, and found that health authorities across the globe have failed to protect millions of patients from poorly tested implants. The investigation found that when flaws are found in medical devices and safety alerts and recalls are triggered, all too often these warnings fail to reach doctors and patients. Recalls, withdrawals and bans on devices are not uniformly applied from country to country, causing confusion and raising risks to patients where insufficient action is taken.

The *Implant Files* state that "Doctors and manufacturers often fail to report adverse events, and when they do the information can be unverified and incomplete. And over large swaths of the planet, health authorities refuse to disclose information about harm to the public — or just never collect it in the first place."[3]

New Zealand was one of the countries specifically mentioned. New Zealand regulators facilitated significant harm to New Zealanders because they failed to do their jobs properly!

The Therapeutic Products Bill represents not only the means by which our lawmakers can ensure that we have a regulatory regime that protects our citizens from dangerous implantable medical devices, but might place New Zealand in a position to lead the rest of the world to a better future for everyone who is recommended an implantable device by their health practitioner.

We are extremely disappointed in the transitional provisions in this Bill (Section 10 of Schedule 1). This Bill may not come into force until the 1st of September 2026, to allow for time for the secondary legislation to be developed. Therefore, under clause 3 (d) (i) of Section 10, the temporary market authorisation for a medical device that was a medical device under the 1981 Act, and under Medicines (Database of Medical Devices) Regulations 2003, will **have up to three years** before that temporary market authorisation expires! Thus, consumers will conceivably have to wait another six and a half years from now (March 2023) to see implantable medical devices sufficiently regulated to give some assurance of safety.

The *status quo* on implantable medical devices effectively continues until September 2029!

This provision MUST be amended! There MUST be recognition that implantable medical devices are already substantially improperly regulated and, as a result, inflict considerable harm on New Zealanders. There MUST be the enactment of stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm and provide for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act. All new devices MUST be subject to the more rigorous regulatory regime that will be introduced when the Therapeutic Products legislation is enacted.

Already in this Bill implantable medical devices have weaker legislation and regulation than prescription medicines. For example, in Section 69 we fail to understand why dispensing, prescribing, administering and possessing a prescription medicine is a controlled activity, but implanting an implantable medical device is not a controlled activity. Implanting a medical device is the corollary of prescribing or administering a prescription medicine and should be subject to similar regulations and controls. However, those controls should be, if anything, more stringent. If adverse effects are suffered as a result of prescription medicine, the first response is to stop taking the medicine. However, with implantable medical devices, they often cannot easily be removed if at all – some, such as Essure contraceptive devices, are designed to never be removed. Others, such as surgical mesh, may only be able to be partially removed and few if any surgeons in New Zealand have the skill and knowledge to do so.

3 ICIJ, 2018: Medical Devices Harm Patients Worldwide As Governments Fail On Safety, The Implant Files, International Consortium of Investigative Journalists.

It is imperative that surgeons implanting medical devices are properly trained, proctored and mentored for device implantation surgery (and removal), and are not permitted to rely on their original surgical training for new devices. Section 27, subsection 3 should be applied to ensure the safety of consumers and that all medical device implanting surgeons are competent and credentialled to undertake implantation surgery and provide the required follow-up.

For example, there is clear evidence that a large part of the problem of injury from surgical mesh in New Zealand is that many surgeons do not have the competence to use it for pelvic organ prolapse and stress urinary incontinence, and that many of the women who have suffered mesh injury have had mesh implanted by inadequately trained surgeons. Hence, the very belated credentialling of surgeons who call themselves uro-gynaecologists.

Concerns around the mechanical and device characteristics of surgical mesh implants is increasing, as is evidence found in clinical research regarding biocompatibility issues. If implantable devices were use-restricted in terms of the training and competence of surgeons (Subsection 3, clause a), or if mesh had been prevented from being used in some procedures (Subsection 3, clauses b and c) there may be far fewer women living with chronic pain and disability.

In the recent hearing of evidence by the Health Select Committee on Sally Walker's petition to suspend the use of surgical mesh for stress urinary incontinence, Dr Eva Fong[4]submitted that surgeons in New Zealand were not competent to implant mesh safely. Dr Fong has treated over 300 New Zealand women with mesh complications from 76 implanting surgeons, including New Zealand's most "experienced" surgeons.[5] In a paper published in the journal *Urology* in 2022, Dr Fong and Dr Hazel Ecclestone found that there were significant short-comings in diagnosis and follow-up in patients who had mesh sling surgery in New Zealand, and that surgeons often fail to recognise and diagnose problems when they occur.[6]

It is vital that there be a separate, dedicated implantable medical device register. Consumer advocates who have been working for over a decade to address a range of issues arising from devastating harm caused to New Zealanders by surgical mesh have been calling for a mesh registry for many years. Surgical mesh injury perfectly illustrates the need for an implantable medical device registry.

A 2016 Health Select Committee report, on a petition for an independent inquiry into safety issues regarding surgical mesh, recommended investigating options for establishing and maintaining a centralised surgical mesh registry.[7] The MoH commissioned a benefit:cost analysis for the establishment and maintenance of a clinical quality register (CQR) for surgical mesh. The proposed register would continually monitor and improve surgical outcomes, resulting in lower treatment cost, mortality and morbidity, and had a benefit to cost ration of 3:1.Error! Bookmark not defined.

Surgical mesh is not the only implantable medical device to inflict devastating harm upon health consumers; others include the Essure contraceptive device, breast implants, lung sealant, deep brain stimulators, hip joint replacements, among many others.[8] The is clear evidence that a register for all implantable medical devices is critical to ensuring patient safety. In 2018, the UK Royal College of Surgeons said that there must be a compulsory registry of all new implantable medical devices.[9]

The development of the register and regulations about the information required to be included, must involve consumers at the beginning. Past regulations on medical devices (Medicines (Database of Medical Devices) Regulations 2003) were woefully inadequate and in part contributed to the surgical mesh crisis, and no doubt have contributed to harm caused by other devices such as Essure and breast implants, among others. The implantable

4 Dr Eva Fong, urologist, current Chair of the Female Urology Special Advisory Group of the Urological Society of Australia and New Zealand, member of the Mesh Complications Committee of the International Incontinence Society.

5 Oral submission of Dr Eva Fong to the Health Select Committee on the petition of Sally Walker to suspend the use of surgical mesh for stress urinary incontinence, as in video of the hearings (at 41 minutes). 15 February 2023.

6 Fong E and Ecclestone H, 2022: Quality of Pre-operative Assessment for Mid Urethral Slings in Women Who Present With Mesh Complications. Urology. 2022 Oct;168:90-95

7 DAE, 2018: Surgical Mesh Registry: Cost Benefit Analysis, Deloitte Access Economics, commissioned by the Ministry of Health, 24 September 2018.

8 Godlee F, 2018: Why aren't medical devices regulated like drugs? *BMJ* 2018;363:k5032.

9 Coombes R, 2018: Surgeons call for compulsory registers of all new medical devices, *BMJ*; 2018 Nov 26;363:k5010.

medical devices register must include data for every single device implanted, including patient/consumer data (redactable/anonymised for all but the Regulator), implanting surgeon/health practitioner, serial numbers, bar codes etc. as well as follow-up notes and facility to include PROMs and harm/adverse events/effects related to the device.

7. Direct to consumer advertising

Direct to consumer advertising (DTCA) must not be allowed to continue. The harm resulting from DTCA is clear, as is the strong opposition from much of the medical community and majority of New Zealanders. It is alarming that policy makers, advisors and/or those writing the Therapeutic Products Bill seem to have been unduly influenced by those with vested interests. The lobbying of those with a vested financial interest in seeing the continuation of DTCA, most notably the pharmaceutical industry has put money ahead of patient wellbeing.

Consumer Advocacy Alliance strongly supports the removal of DTCA for the safety and wellbeing of consumers.

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