TINZ Submission
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Submitted to **Therapeutic Products Regulatory Scheme: Online Consultation**
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Chapter A Key features of the new regulatory scheme (A1 - A5)
Comments:

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

1. Transparency International NZ submits that 3(b) should include 'adaptation' and 'withdrawal or removal' in the list, to be certain to capture the greyer areas of therapeutic product management, and the areas where a lot of problems seem to occur.

2. Transparency International NZ understands that a weighting of benefits over risks may be to support flexibility and innovation. However this requires balanced ording to ensure that the management of risk is sufficiently dealt with. We do not see that in the wording of ss4, where (b) (i) is somewhat overshadowed by (a).

   We suggest the inclusion of a clause which will have the direct effect of requiring a more active and dynamic approach to risk (including monitoring and skilled and timely responses) where the detrimental health impact is high, even if those cases are in a minority.
   For those individuals the result can be catastrophic.

B4 Part 2 of the Bill: Interpretation
Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).:

3. Transparency International NZ queries whether the application of medical devices is adequately covered under the draft legislation. Two areas which have generated considerable injury and trauma are the insertion, implantation, and then removal of medical devices through surgery.

   In the list of controlled activities under 10(2) one assumes removal is included under use.
   It does not appear to be sufficiently covered in there or in section 53?

4. Ss 22. Transparency International supports the submission of Mesh Down Under' which states that:
   "Access restrictions need to be established and applied to BOTH medical devices and medicines.
   The reasoning and wording in this paragraph is too loose and is a clear loophole,
   "the scheme would enable supply restrictions and/or use restrictions on a device or class of devices".

For the regulator to be able to determine 'safety concern' they need to follow a lengthy complicated process which is extremely convoluted and can last for many years.
To substantiate this proof of evidence, the NZ regulator would need to rely on overseas regulatory bodies for 'evidence'. Using the surgical mesh issue as an example, there is clear evidence documented (globally) showing how overseas regulatory bodies have used flawed clinical research to base their decisions on for approving devices. It is understandable that there is a strong pushback from industry to validate the safety of their products, which includes documented conflicts of interest from industry with close links to international regulatory bodies.

The surgical mesh issue is the perfect example of how even when serious safety concerns about patient safety are evidenced it takes years for any action to be taken to address serious safety concerns."

It is important to ensure that a categorisation system be introduced for devices as well as medicines, both need the same level of scrutiny and legislative mechanism.

B5 Part 3 of the Bill: Dealing with therapeutic products

Subpart 4: Other offences (ss 81-94)

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

5. Transparency International NZ comments on DTCA later in this submission but not specifically on the offences.

Section 88.

6. Transparency International NZ also agrees with Mesh Down Under in relation to Misrepresenting a therapeutic product (ss 88)- Within the TPGB there have been no provisions made which relate directly to the advertising of procedures, unfortunately only therapeutics products have been included.

   Consideration regarding the inclusion of procedures is needed. Specifically, the language used in any information which is provided to the public, must be a balanced representation which details all risks as well as the positive impacts and this needs to be extended to information provided in video format or electronic media.

   There also does not seem to be a clear enough distinction as to what is specifically classed as an advertisement or article. One example of this is the article/advertisement, which was placed in the Listener in 2015, called the Leaky Person Syndrome. It is very unclear as to whether this is an article or advert, but regardless the information should not be misleading.
   The focus for the advert/article was for women suffering with stress urinary incontinence, sadly only the positives of surgical mesh were highlighted with no mention of any risk at all about the procedure included, nor alternative surgical options provided. At the time of publication, there was plenty of clinical research and evidence which demonstrated serious concerns regarding these procedures and our petition to parliament for an inquiry into the issue had been accepted in parliament and was under review. These devices and procedures were already known as high risk but none of these risks were mentioned.

A clear distinction needs to be made as to what constitutes an advertisement or article and we need to ensure that procedures are included in any legislative changes made.
Please read this link: https://www.noted.co.nz/health/health/leaky-person-syndrome/

Section 93. Health practitioner prescriber must not hold interest in a pharmacy business .

7. Transparency International NZ supports the submission of Mesh down Under where it argues that this clause only applies to pharmacy and medicines. It should also extend to health practitioners who may have a commercial incentive for a medical device, since they have the same potential financial benefits which could lead to basing clinical decisions resulting from a conflict of interest. Strengthening the legislation so it is extended to health practitioners using devices is important- at the very least they should tell the patient that this commercial incentive exists, but, although this is already an expectation this needs to be able to be mandated and included in the legislation.

B6 Part 4 of the Bill: Product approval
Subpart 1: Approval of products (ss 94–113)
Question B13.
Please provide any comments on the sections covering product approval requirements (ss 94–104).:

8. Transparency International supports the submission of Mesh Down Under' which also applies to ss 95. How will known loopholes affecting decisions on approval be identified and addressed?

9. Criteria for approval- "safety and performance of a device to be satisfactorily established"
This is difficult to ascertain if a product has come through the 510k process and is subject to criteria of approval only based on a predicate device. In many cases the predicate device that this new device has received approval through, has also gone through this same process.

This 510k approval pathway is not robust enough to ensure the safety of these products and history has shown that the risks cannot be 'satisfactorily established.' As an example, the Protogen Sling made by Boston Scientific in 1996 had a very high complication rate and was recalled in 1999. The FDA stated that "Use of ProteGen in the treatment of female urinary incontinence is associated with higher than expected rate of vaginal erosion and dehiscence and does not appear to function as intended".

Ironically the Protegen itself was approved through the same 510k process, yet the predicate devices it was based on were not made of the same material (polypropylene) and the surgical approach to implant this device was completely different. (see second link below)
The TVT which is the most commonly used surgical mesh device in NZ currently, is based on the ProtGen predicate device. Of great concern, the FDA have no authority to remove a subsequent device which has been based on a predicate device and has been subject to a level one recall (because of safety concerns). Globally the most serious device related issues and majority ofproblems that have been associated with medical devices, have come about because of this process. Although the FDA are strengthening their guidelines this 510k process remains.

Question B14
Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113):

10. Transparency International strongly supports the requirement for a register of medical devices to be held by the regulator including those that have been approved and those that have been refused approval.

Subpart 1: Regulatory powers and functions(ss 160–182)
Question B24
Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).:

11. Transparency International NZ promotes transparency and integrity. We support the regulator promoting openness, ethical behaviour and ethical leadership which will lead to improved public trust and confidence. We strongly support the regulator requiring timely registration of all clinical trials, and reporting of results, not just those that are publicly funded.

    It should also be the role of the regulator to apply standards and requirements on relevant random controlled trials.

    We strongly promote openness, which means publishing of decisions about declined product approvals, removal of product approvals and results of all trials including those that have negative outcomes.

    We strongly support engagement by the regulator with consumers as well as other stakeholders, so that it can be responsive to a range of community voices as well as business and medical professionals.

C4 Clinical trial sector
Question C16
Please provide any comments on the change in approach to regulating clinical trials.:

12.

a. Transparency International NZ joins Mesh Down Under and TranspariMED in their call for the NZ government, via the Ministry of Health to sign the World Health Organisation (WHO) joint statement on public disclosure of results from clinical trials.

b. There are many good reasons for increased transparency of clinical trials, not least that regular and prompt updating of registry data enables patients to locate the trial they are registered on and makes it easier to recruit patients. Whilst there have been significant improvements in the registration of clinical trials there are still big gaps, including around random control trials. We need more effective rules to support industry and regulatory engagement.

Another way of increasing transparency is for all NZ trials to be published regardless of whether there is a positive or negative outcome. This is not currently the case. If trial outcomes and summary results are not published, there is a risk that valuable research findings are wasted because they are not available to the scientific and clinical community.

This can also result in harmful drugs and devices being marketed which brings patient safety into question.

c. Clinicians and health consumers need to be aware of negative trial outcomes, so that they can make informed decisions about procedures and devices they use or accept to be used on them.

d. Ethics approval should be mandatory for all clinical trials and for most random controlled trials. Although there has been advances in this area, the report from the ANZCTR clinical trial registry notes that "only 50% of trials prospectively registered had ethics approval at the time of registration. (2006-2015)" refer to ANZCTR Clinical Trial Landscape Report. (ss419)-

Question C53
Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?:

13.

a. Transparency International NZ has a firm view that Direct to consumer advertising should not be permitted. This would bring New Zealand into line with international best practice.

b. We are surprised that a separate and full review including research and independent reviews has not been undertaken. This would complement the general consultation on the Therapeutic Products Bill. The Ministry's pre-stated position on this issue is perplexing given time time lapse since the 2006 report when the Ministry also didn't form an opinion.

c. There is considerable international research available. In the 2006 review the majority of government agencies, educational/research agencies, members of public and consumer groups opposed dtca. Dtca was unanimously supported by advertising agencies and pharmaceutical companies, and the opinions of health professionals making submissions were divided.

d. We note that since 2017 the Royal NZ College of General Practitioners has supported a full ban on dtca.

Aside from the RNZCGP statement, there are two good relatively recent discussions on the issue:
a) Every-Palmer, Duggal and Menkes in NZMA Journal, 29.8.2014, Vol 127 No 1401
https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/Position-Statements/2017.03-DTCAPositionStatement.pdf

b) Helena Jochem 'Direct-to-Consumer advertising for prescription drugs in New Zealand: Time for

a Radical Change? LLM Research Paper Laws 432/532,
Consumer Law, Victoria University 2015.

e. Considering the changing views in society it would have been useful had the Ministry, in taking its position not to propose a change to the law, provided a more considered paper on the topic, setting out its reasons for its preliminary position, or at least acknowledging gaps in evidence and how they plan to address that.

f. There is certainly international evidence about the failure of dtca to report details about the drug's mechanism of action, success rate, treatment duration, alternative treatments and any behavioural changes that could enhance the health of affected patients. Dtca has also been linked with inappropriate prescribing and overtreatment.

Despite the aim for the Bill to make sure the ads were "truthful, not misleading and socially responsible" it is likely that in environment of 'accentuate the positive' an advertiser is unlikely to provide a balanced view.

Question C56 - Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.:

14. Consumers of therapeutic products may be experiencing distress, urgent need, and sometimes in fragil e health, when they interface with the products and the people who sell and use them. This generates a power imbalance. They are usually competent and able to understand complexity and to make decisions. This places a particular onus on those who hold power – prescribers, therapeutic product producers, advertisers, medical professionals and regulators – to act with integrity, and particular care, and to provide clear explanations of options and risks, and including alternatives to the use of products.

15. Most medical professionals and therapeutic product producers, and policy makers would benefit from training provided by disabled people that would support their ability to ensure that people with disabilities have informed choice, and receive care of the same quality as others, including on the basis of free and informed consent. This is entirely in keeping with NZ's commitment to the International Convention on the Rights of Persons with Disabilities.

End of Submission