consumer.

5 March 2023

Committee Secretariat
Health Committee
Parliament Buildings
Wellington

SUBMISSION on Therapeutic Products Bill

1. Introduction

Thank you for the opportunity to make a submission on the Therapeutic Products Bill (the Bill). This submission is from Consumer NZ (Consumer), an independent, non-profit organisation dedicated to championing and empowering consumers in Aotearoa. Consumer provides fair, impartial and comprehensive consumer information and advice.

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We wish to speak to our submission.

2. General comments on the Bill

In general, we support the Bill. We are very pleased sunscreens will be included as a therapeutic product under the Bill and regulated under the regime. We have been calling for this for many years so are extremely supportive of this move.

We are also very pleased to see the inclusion of natural health products in the Bill. We agree the current regime does not provide adequate levels of assurance that these products are safe or made to appropriate standards. We also agree the current regime does not adequately regulate health claims made about natural health products.

We support increased regulation of medical devices, as proposed by the Bill. In our view, this is likely to improve consumer protection from unsafe and ineffective products.

However, we are very disappointed the Bill does not include a ban on direct-to-consumer advertising of medicines (DTCA) and urge the Health Committee (the Committee) to reconsider its position on DTCA.

We discuss each of these issues in further detail below.

3. Specific comments on the Bill

Sunscreens

Consumer is pleased the Bill will regulate sunscreens as a therapeutic product and repeal the Sunscreen (Product Safety Standard) Act 2022.

Consumer has been campaigning for sunscreens to be regulated as a therapeutic product for many years. Exposure to excessive UV radiation is a major risk factor for skin cancer. Sunscreen reduces this exposure, so it provides a therapeutic purpose – preventing DNA damage and the development of skin cancer.

Clause 63 of the Bill states that the rules may set out standards (product standards) for therapeutic products and we recommend a product standard is maintained for sunscreens.

The standard should require sunscreens to comply with the most recent version of the Australian and New Zealand standard (AS/NZS 2604 Sunscreen Products – Evaluation and Classification). This standard includes procedures for determining sunscreen product performance and classification (including procedures for determining the Sun Protection Factor, broad spectrum performance and water resistance), and explicit requirements for labelling (including instructions on how to apply the product).

Consumer also recommends the standard stipulates requirements for testing frequency as we believe the requirements of AS/NZS 2604 are not sufficient to protect consumers. The standard does not specify how often a sunscreen should be tested and our investigations have found some companies regularly relying on tests that are several years old. In our view, testing should be required at least annually or biannually. It should also be required whenever there is a new batch or formula change.

Responsibility for ensuring testing is robust and current should not lie with the government or consumer agencies, such as Consumer. However, the standard's lack of requirements for routine testing have helped create a situation in New Zealand where some manufacturers are only addressing compliance issues in response to testing conducted by Consumer, with support from the Ministry of Health. The fact the standard does not require manufacturers to regularly test their products is a significant oversight and the standard is clearly failing consumers in this respect.

We would like to see the provisions of the Bill related to sunscreens come into effect as soon as possible. However, we consider the complexity of the Bill may prevent this from happening. We therefore suggest the Committee considers whether it might be appropriate to split up the Bill to ensure progress isn't delayed. Splitting the Bill may also provide greater overall clarity as it would be easier to set clearer purposes for each individual piece of legislation.

Natural health products

Consumer is pleased the Bill will regulate natural health products as part of the therapeutic products regime and repeal the Dietary Supplements Regulations 1985.

Consumer strongly supports the changes in the Bill requiring a market authorisation for natural health products. New Zealanders are regular consumers of natural health products. In 2022, New Zealanders spent $135 million on vitamins, minerals and herbal extracts at the supermarket, according to scan data supplied to Consumer by Nielsen IQ.

We agree natural health products should be evaluated against different standards than those for medicines and medical devices.

In a recent survey[1] of people who take natural health products, Consumer found that only one-third of shoppers (33%) said they often or always research product claims before they buy a natural health product. Just over half (52%) of respondents agree they can trust the labels, while 10% don't trust the labels.

[1] Our data are from a nationally representative survey of 1001 New Zealanders, aged 18 and over, and carried out in November 2022.

Therefore, Consumer strongly supports clause 61 that defines health benefit claims and permitted health benefit claims, and clause 62 that will set out the claims that can be made about a natural health product.

We note that under clause 62 of the Bill, a person may apply to the Regulator to have the rules amended, to add or amend a standard health benefit claim. We recommend that in these situations there must be a detailed framework for the substantiation of health benefit claims, which should include a systematic review.

The Regulator must give clear guidelines on how a systematic review should be conducted, including the types of studies that must be included. Emerging studies should not be sufficient to support a health benefit claim. An example of a useful framework can be found in the Schedules of the Australia New Zealand Food Standards Code.

We strongly support clause 63 of the Bill which requires the Regulator to keep a publicly available register of therapeutic products, including natural health products.

We are pleased the Bill references the requirement for the Regulator to have a post-market surveillance and response system for all therapeutic products. We believe this is particularly important for natural health products and sufficient funding must be allocated for monitoring compliance of health claims. Without this, the system will be less effective at protecting consumers.

To assist enforcement, we'd like to see a publicly accessible complaints process so it's easy for consumers to make a complaint. This must be in addition to proactive monitoring by the Regulator.

Medical Devices

As stated in previous submissions, we support increased regulation of medical devices. In our view, there isn't enough scrutiny of these types of devices. This lack of scrutiny can result in harm to consumers.

For example, devices such as the "Pain Erazor" (pictured below) have been supplied in New Zealand for years, without evidence to back up their efficacy.

The "Pain Erazor" claims to stimulate the body's release of endorphins for fast pain relief. The device claims to work through "the science of electro-analgesia", utilising the body's own natural response system to relieve the effects of pain.

However, a Consumer investigation in 2017[2] into the claims found it is unclear whether the use of electrical current is a reliable method of pain relief. We also recently ran a trial[3] of the device and although it provided short-term pain relief to some trialists, others found the device made their pain worse.

The Pain Erazor did not go through any pre-market assessment or approval process before it hit the shelves. In our view, this needs to change. Medical devices should not be allowed to be marketed to consumers unless there is sufficient evidence to back up their safety, quality and efficacy.

We therefore strongly support the changes in the Bill requiring a market authorisation for medical devices before they are imported into, exported from, or supplied in, New Zealand.

[2] https://www.consumer.org.nz/articles/pain-erazor-claims
[3] https://www.consumer.org.nz/articles/consumer-nz-tv-shop-customers-beware

Direct to Consumer Advertising

Even though the Bill sets out harsher penalties for non-compliance, we do not support the fact that the Bill will continue to allow DTCA.

As stated in previous submissions, we strongly oppose DTCA and have been calling for a ban on it for many years. There is also strong support for a ban of DTCA from many other reputable organisations.

In our 2019 submission, we stated our view that DTCA should be banned for the following reasons:

- Advertisements don't provide all the information required for consumers to make an informed decision.
- DTCA increases the risk of inappropriate and unnecessary prescribing, creating health risks for consumers.
- DTCA results in increased costs for both consumers and the health system.
- The current system of self-regulation is not effective.
- DTCA has already been banned in many other countries due to the risks it creates for consumers. New Zealand and the USA are the only two countries in the developed world that allow DTCA. New Zealand consumers deserve the same protection as those in countries that have banned the practice.

Many consumers also support our call for a ban on DTCA. In our latest research on DTCA[4], we asked consumers whether they supported a ban on DTCA in favour of a health information service that provided independent advice about health treatments. Forty four percent said yes, showing clear support for a ban. Only 29% didn't support a ban and 27% didn't know.

Finally, we consider the reasoning for continuing to allow DTCA is flawed and support the arguments put forward by Joel Lexchin, Barbara Mintzes and other academics in their submission.

We urge the Committee to reconsider a ban on DTCA.

Thank you for the opportunity to provide comment.

ENDS

[4] Our data are from a nationally representative survey of 1001 New Zealanders, aged 18 and over, and carried out in November 2022.