17 April 2019

Therapeutics Products Regulatory Scheme Consultation
Ministry of Health
PO Box 5013
Wellington 6140

By email: therapeuticproducts@moh.govt.nz

SUBMISSION on
"Therapeutic Products Regulatory Scheme"
Consultation Document

1. Introduction

Thank you for the opportunity to make a submission on the "Therapeutic Products Regulatory Scheme" consultation document. This submission is from Consumer NZ, New Zealand's leading consumer organisation. It has an acknowledged and respected reputation for independence and fairness as a provider of impartial and comprehensive consumer information and advice.

Contact: Aneleise Gawn
Consumer NZ
Private Bag 6996
Wellington 6141
Phone: 04 384 7963
Email: aneleise@consumer.org.nz

2. General comments

We agree the Medicines Act is outdated and we support the introduction of a more modern and comprehensive therapeutic products regime.

We have focused our comments on three main issues:
- the regulation of sunscreens
- the regulation of medical devices
- direct-to-consumer advertising (DTCA) of prescription medicines.

3. Answers to questions

Question B2 – Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14-50).

We strongly support the inclusion of sunscreens in the definition of therapeutic products. We recommend:
- the definition include all primary sunscreens (products used primarily for protection from UV radiation with an SPF of 4 or more) and other products such as moisturisers containing sunscreen active ingredients and claiming an SPF rating.
- sunscreens be required to comply with the Australian and New Zealand standard AS/NZS 2604:2012 Sunscreen Products – Evaluation and Classification.
- regulations specify how often sunscreens must be tested and include requirements regarding the testing laboratories that companies can use to validate efficacy.

- the regulator carries out monitoring of products (including independent testing) to ensure label claims are truthful.

Current situation

New Zealand has one of the highest rates of melanoma (39.4 per 100,000 for men and 35.8 per 100,000 for women) and non-melanoma skin cancers (estimated to affect one in two males and one in three females before the age of 80) per population in the world. It is estimated the direct healthcare treatment costs of skin cancer are more than $57 million.[1]

Exposure to excessive ultraviolet (UV) radiation is a major risk factor for skin cancer. Sunscreen is one method of protection to reduce exposure to UV radiation, and prevent DNA damage and the development of skin cancer.

Despite this, the Australian and New Zealand sunscreen standard AS/NZS 2604:2012 is voluntary. Sunscreens that meet other international standards, such as those in the US or EU, are allowed to be sold in New Zealand, as well as sunscreens that don't meet any standard.

The current situation means consumers may be using products that have undergone no testing and do not meet their label claims. This is not acceptable in a country with high skin cancer rates.

Summary of our test results

We have been testing sunscreens for more than 10 years and continue to find products that don't meet their label claims.

In 2018/19, we commissioned testing of the SPF protection and broad-spectrum protection of 19 sunscreens. SPF measures a sunscreen's protection against sunburn caused mainly by UVB radiation and is assessed on a panel of 10 human subjects. Broad-spectrum measures the UVA protection passing through a thin film of sunscreen on a plate.[2]

Eighteen sunscreens passed the broad-spectrum requirements (one company had a partial fail). However, only four of the 19 products met SPF label claims in our test.

We sent test results to the manufacturers and asked what evidence they had to substantiate their claims.

- Four companies did not provide any evidence.
- Two companies confirmed their products had not been tested on human subjects.
- One company provided incomplete testing (SPF testing only undertaken on one test subject).
- Eight companies provided test results from US laboratories to support SPF label claims. However, one set of test results dated back to 2013, and two sets of results were from 2015.[3]

Testing in previous years has identified similar problems.

---

[1] https://www.sunsmart.org.nz//sites/default/files/documents/FINAL-Strategy-2017-to-2022.PDF

[2] Eurofins Dermatest (an accredited laboratory in Australia) conducted the testing following the Australian and New Zealand sunscreen standard AS/NZS 2604:2012.

[3] We are also concerned about the uniformity of test results provided by these laboratories. Because SPF testing is carried out on human subjects, it would be unusual for multiple results to be identical. However, this is what we sometimes see in test data provided to us.

In 2017, we tested 19 sunscreens. Our test found:

- Only nine products met their SPF label claim and passed broad-spectrum requirements
- Two products failed broad-spectrum requirements.

As a result of this test, three "natural" products were removed from sale. Two of these products only provided low protection (SPF 4 to 14) and had not been tested on humans. The third product had not been tested and the claimed SPF was based on test results for a similar product.

Our 2017 test raised concerns about the efficacy of products branded as "natural" sunscreens. As a result, we conducted a market survey that identified 32 natural sunscreen brands. We asked each company to provide a test certificate to support its label claim. Only six of the 16 brands that responded provided ten-subject test certificates to support SPF label claims and evidence of broad-spectrum compliance.

In 2014, we tested 12 sunscreens. Seven products didn't met SPF label claims, two failed broad-spectrum requirements and two others partially failed.[4]

Mandatory compliance with AS/NZS 2604:2012

In Australia, primary sunscreens must comply with AS/NZS 2604:2012, which includes requirements for labelling, UVA (broad-spectrum), SPF and water resistance. Sunscreens must also be listed on the Australian Register of Therapeutic Goods and be manufactured in accordance with the principles of Good Manufacturing Practice. Once a product is listed, a company must provide evidence its sunscreen has been tested by a registered laboratory and complies with AS/NZS 2604:2012.

We recommend making it mandatory for sunscreens to comply with AS/NZS 2604:2012. However, we do not believe this alone is sufficient. The standard does not specify how often sunscreens should be tested so some companies are relying on tests that are several years old.

We consider companies should be required to regularly test sunscreens, either annually or every batch. New testing must also be carried out when there is a formulation change.

Additional monitoring

In Australia, the Therapeutic Goods Administration (TGA) is the regulator for sunscreens. It carries out laboratory testing and desktop reviews of some products. Its laboratory testing carried out in 2017 measured the levels of active ingredients specified on product labels. Its desktop review published in 2018 looked at product labels, manufacturing and formulation data, and SPF-testing data provided by the company.[5] Neither the lab testing nor the desktop review included independent testing in accordance with AS/NZ 2604:2012.

We consider the New Zealand regulator should carry out testing in accordance with the standard to ensure consumers are not misled about the products they are buying.

[4] For more information, see consumer.org.nz/articles/sunscreens.

[5] See https://www.tga.gov.au/community-qa/tgas-compliance-review-sunscreens.

Regulation of medical devices and comments on question C11 - Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated?

We strongly support increased regulation of medical devices to improve consumer protection from unsafe products.

We also consider regulation needs to be improved to prevent products that lack efficacy data being promoted to consumers. One example is the Pain Erazor, a product widely advertised on television and in other media. Our investigation of this product found no robust evidence to support the health claims being made.[6]

Existing rules mean there is little regulatory scrutiny of these types of devices. There is no pre-market assessment or approval process required before a product is sold. No studies have to be filed to support product claims or prove efficacy. The company supplying the product only has to register it on Medsafe's online database.

In their product promotion, manufacturers may claim registration on this database provides evidence the product has been through a rigorous approval process. However, this is not the case and consumers are being misled about the evidential basis for the health claims made.

We also support regulation of products such as dermal fillers and other products used for cosmetic purposes. While these products don't have a therapeutic purpose, they carry significant health risks for consumers. We therefore consider they should be included in the legislation.

The EU has moved to regulate these products. Australia is also looking at making similar changes to its therapeutic goods administration regime.[7]

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?

We strongly oppose DTCA. We have been calling for a ban on DTCA for many years. There is also strong support for a ban from the Council of Medical Colleges of New Zealand, the New Zealand Medical Association, New Zealand Nurses Association, the Public Health Association of New Zealand, the Royal New Zealand College of Urgent Care Physicians, the Royal Australian and New Zealand College of Psychiatrists and the Royal New Zealand College of General Practitioners.

We consider DTCA should be banned for the following reasons:

- Ads 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 consumers deserve the same protection.

[6] https://www.consumer.org.nz/articles/pain-erazor-claims

[7] https://www.tga.gov.au/consultation/consultation-changes-number-definitions-and-scope-medical-device-regulatory-framework-australia

These points are discussed further below.

Insufficient information to make an informed decision
Drug companies claim DTCA helps consumers by increasing awareness of drug treatments and medical conditions.

However, DTCA does not provide all the information required for consumers to make an informed decision. Our research has found information in ads can be unbalanced and incomplete. Examples provided in the appendix illustrate that important information about side effects can be buried in fine print, making it difficult for consumers to fully understand the risks involved in taking the medicine.

The ads also promote only one possible solution to a health problem. They do not provide a comprehensive overview of treatment options, nor do they discuss the benefits of non-drug treatments, making healthier lifestyle choices or the likely efficacy of the drug. Instead, ads convey the message there is a "quick fix" to health issues.

For example, an advertisement for Zarator (a prescription medication to lower cholesterol) states "thousands of Kiwis take it", conveying the impression it's normal to take the drug, even for those who may be better off making lifestyle changes to reduce their cholesterol levels.

A recent study published in the *Australian and New Zealand Journal of Public Health* showed those with unhealthier lifestyles were more likely to respond to DTCA, raising concerns that drugs may be used to treat diseases that would otherwise be improved through lifestyle changes.[8]

Drug companies also argue DTCA is beneficial to consumers because it prompts a discussion of treatment options between patients and doctors. However, many doctors oppose DTCA because it can be both difficult and time-consuming to convince a patient that a particular drug is not appropriate for them.

Doctor-patient relationships can also be affected if the doctor refuses to prescribe a specific medicine. Some consumers may seek the medicine elsewhere.

Increased risk of unnecessary prescriptions and overtreatment
Proponents of DTCA argue doctors are the gatekeepers who make the final decision about whether a particular drug is suitable for their patient. However, DTCA puts pressure on doctors to prescribe particular medicines. This can result in inappropriate and unnecessary prescribing decisions, creating health risks for consumers.

Prescription medications are only available by prescription for a reason. That is, they have physiological effects that can be dangerous or even lethal. Unnecessary prescribing can also result in polypharmacy – the concurrent use of multiple medicines by one individual. Polypharmacy is associated with a higher risk of adverse drug reactions and interactions.[9]

Previous survey research in New Zealand and the United States has shown that when a patient asks for a specific drug, more often than not, they'll receive a prescription for that drug.[10]

---

[8] https://onlinelibrary.wiley.com/doi/full/10.1111/1753-6405.12883
[9] https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/PolicyBriefDeprescribingMay2016updatedSept2016.pdf
[10] https://www.nps.org.au/australian-prescriber/articles/the-impact-of-advertising-prescription-medicines-directly-to-consumers-in-new-zealand-lessons-for-australia

According to one study comparing prescribing behaviour in Canada and the United States, American consumers were more likely to believe they needed medication, request advertised medicines and receive prescriptions for these medicines.[11]

In New Zealand, Brandworld, the marketing company behind Family Health Diary, claims 94 percent of pharmacists consider it has increased sales and 99 percent reported fielding customer inquiries about advertised products.[12]

According to Medicines New Zealand, 33 prescription medicines were advertised in New Zealand in 2018. Pharmaceutical companies are estimated to spend tens of millions of dollars per year on drug advertising in New Zealand.[13] In our view, companies wouldn't be investing in advertising if it didn't result in higher sales.

Increased cost to consumers and the health system
In addition to inappropriate prescribing, DTCA can also result in unnecessary and inappropriate expenditure for both consumers and the health system.

If an ad prompts a consumer to visit their GP, the consumer not only faces the cost of the appointment, but also the cost of the medication, which they may or may not need. In addition, the consumer may be prescribed an expensive branded medication that offers little or no benefit over a cheaper generic brand.

With subsidised medicines, there are also costs to the healthcare system from inappropriate prescribing. Given the limited health budget, inappropriate prescribing reduces resources available and means consumers miss out on other health services or products.

Current system of self-regulation ineffective
In our view, the current system of self-regulation is not effective. The Therapeutic Advertising Pre-vetting System (TAPS) does not involve any technical pre-vetting of the accuracy or balance of the scientific basis for the claims made in the ad. Some companies can also apply to pre-vet their own advertisements.

In addition, no organisation actively monitors drug promotion in New Zealand. Investigations of breaches of the Therapeutic and Health Advertising Code only occur as a result of written complaints. The complaints process is difficult and time-consuming, and the penalties limited.

Examples provided in the appendix include ads that we consider contain incomplete information about the drugs' efficacy and adverse side effects. In our view, these ads provide evidence the current system is not working in consumers' best interests.

DTCA banned in most other countries
New Zealand and the United States are the only industrialised countries that permit DTCA of prescription medicines. The reason other countries have banned this type of advertising is because of the harmful effect it has on rational prescribing, pharmaceutical expenditure and health outcomes.

---

[11] Cited in https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1401/6278
[12] Cited in https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1401/6278
[13] https://www.ncbi.nlm.nih.gov/pubmed/17916850

We support a similar ban in New Zealand.

Thank you for the opportunity to make a submission on the consultation document. If you require any further information, please do not hesitate to contact me.

Yours sincerely

Sue Chetwin
Chief Executive

Appendix

Ad for Anoro Ellipta (for COPD): advertising only mentions there are risks in the fine print.

Ad for Celecoxib Pfizer (for joint pain): advertising only mentions there are risks in the fine print.

Ad for Daivobet Gel (for psoriasis): advertising only mentions there are risks in the fine print.

Ad for Duavive (for menopause): advertising only mentions there are risks in the fine print.

Ad for Efexor XR (for depression): advertising displays important messages about risks in the fine print.

Ad for Fucithalmic (for conjunctivitis): advertising mentions possible side effects in the fine print.

Ad for Lantus (for diabetes): advertising describes a consumer with type 2 diabetes who "looked after himself but still had high blood sugar"; only mentions risks in fine print.

Ad for Zarator (for lowering cholesterol): advertising states "Thousands of Kiwis take it" and only mentions there are risks in the fine print.

Ad for Seretide (for asthma): advertising only mentions side effects in the fine print.

Ad for Ventolin (for asthma): advertising promotes the product as a preferred option ("Kiwi parents choose Ventolin") and only lists common side effects in the fine print.

Ads for Kadcyla (for breast cancer) and Gilenya (for MS) only mention risks in the fine print.