Submission on the Therapeutic Products Bill

To: Health Select Committee

5 March 2023

Introduction

This submission is by the Cancer Society of New Zealand (Cancer Society). We are a registered charity working to reduce the incidence and impact of cancer in Aotearoa/New Zealand. We are providing comment as fair and timely access to therapeutic products directly impacts outcomes for whānau/families with cancer.

On a daily basis, our supportive care teams are fielding questions and concerns from whānau/families with cancer about their treatment regime, side effects of medication, how to get treatment not available in Aotearoa/New Zealand, information about alternative medicines, and many others. To year ended 31 March 2022, the Cancer Society's team had 88,006[1] contacts and received 8,814[1] new referrals for whānau with cancer and those supporting others with cancer. This support service is provided throughout the country by teams at the Cancer Society's six regional Divisions.

The Society supports the purpose of the Bill to protect, promote and improve the health of all New Zealanders through the provision of safe, quality, and effective medicines, active pharmaceutical ingredients (APIs), medical devices and natural health products (NHPs).

This Bill has the potential to impact whānau/families with cancer in a number of ways, including -

- Access to rongoā Māori
- Greater protection from sunscreen as a therapeutic product
- Entry into clinical trials
- Access and use of natural health products (NHP) as complementary and alternative medicines
- Importing medicine for personal use
- Use of cell and tissue therapeutic products

Summary

- The Cancer Society supports introduction of a regulatory framework able to consider the safety and quality of NHP across their life cycle.
- The Cancer Society recommends that –
    - an exemption mechanism or an abbreviated regulatory process is provided for clinical trials that involve treatment of a small number of people (e.g. < 50 NZ patients/year) with life-threatening conditions (such as advanced cancers), particularly where the medicines involved have already been through an assessment by competent authorities (e.g. in Australia, Europe, USA), and
    - the new regulator provides fee exemptions for public good clinical trials (e.g. co-operative group trials or those funded by the Health Research Council or Cancer Society), as opposed to trials run principally for the benefit of a pharmaceutical company

- support the purpose of this Bill.

- The Cancer Society asks for further detail on the definition of advertisements to exclude factual information provided to patients and whānau by charities providing support.
- The Cancer Society recommends that access to and use of rongoā Māori is not impacted by increased compliance costs and/or controls on ingredients.
- The Cancer Society recommends that for whānau with cancer, self importation of cancer medicines not available in Aotearoa/New Zealand is clear, readily accessible, timely and at minimal cost to the person with cancer.
- The Cancer Society recommends that the ability to maintain a small stockpile of a medicine so it is available for immediate release once a special clinical needs supply authority has been issued is progressed.
- The Cancer Society recommends special consideration is given to the regulation of CAR T-cell treatment to ensure that the regulatory regime supports this life saving treatment quickly becoming available in New Zealand following the clinical trial.

Why change is needed

Equity and poorer cancer outcomes for Māori

It is well established that Māori are 20% more likely than non-Māori to develop cancer but twice as likely to die from it[2]. Fairness for Māori must be actively addressed in all and every aspect of health care provision, including this Bill. It is encouraging to note the planned engagement with rongoā Māori practitioners to mitigate the unintended impacts of regulation of natural health products. Reduced access to rongoā Māori through increased compliance costs and/or controls on ingredients would be a barrier to achieving the goals of mana Motuhake (the right to make choices that reflect Māori values and practices) and mana Māori (enabling Ritenga Māori that support wellbeing and are encapsulated in mātauranga Māori).

New and evolving cancer treatments

In the field of cancer, it is increasingly common to subset malignancies according to specific genetic changes, and to personalise therapies accordingly. These personalised therapies are increasingly assessed in 'platform trials', in which a large number of new medicines are assessed, each in the small number of patients who are most likely to benefit from them. Niche medicines, such as kinase inhibitors or immunotherapies, are often manufactured by smaller pharmaceutical companies that do not have representation in NZ. These 'platform trials' are often run by international co-operative groups, which are non-profit organisations.

Clinical trials are already highly regulated and are assessed for risk/benefit by ethics committees and (where new medicines are involved) by the SCOTT or GTAC committees relating to new medicines or gene therapies. We are concerned that the requirement for a new regulatory body, with unspecified fees and levies, to regulate medicines imported for clinical trials, plus the need for a local 'sponsor' of a medicine used in a clinical trial, will add major financial and logistical burdens to platform trials of personalised cancer therapies. This risks precluding New Zealanders participating in future co-

operative group cancer trials, as these groups do not have the resources to support extensive regulatory processes and costs for a large number of new medicines each for a small number of NZ patients. This would have a chilling effect on the NZ clinical trial environment in the field of cancer.

To address this anomaly, an exemption mechanism or an abbreviated regulatory process is suggested for clinical trials that involve treatment of a small number of people (e.g. < 50 NZ patients/year) with life-threatening conditions (such as advanced cancers), particularly where the medicines involved have already been through an assessment by competent authorities (e.g. in Australia, Europe, USA), and the fee schedule includes fee exemptions for public good clinical trials (e.g. co-operative group trials or those funded by the Health Research Council or Cancer Society), as opposed to trials run principally for the benefit of a pharmaceutical company.

Ultraviolet radiation causes cancer

Although skin cancer is largely preventable, it is Aotearoa/New Zealand's most common cancer. Every year around 500 New Zealanders die from skin cancer and over 90,000 new cases of skin cancers are diagnosed[3,4]. Along with the personal cost, substantial public healthcare resources are consumed in managing skin cancer each year[5]. Sunscreen is one method of protection used to reduce the risk of skin cancers caused by excessive exposure to UV radiation[6]. New Zealanders should be able to trust the efficacy of the sunscreen product they purchase to provide adequate sun protection. We are concerned that in recent years trust in sunscreen may have reduced.

Given this the Society supports inclusion of sunscreen to be regulated under this Bill as a therapeutic product to ensure sunscreens meet all therapeutic regulatory requirements for labelling, efficacy, safety, and quality, and are accompanied by good information about their use. We support modelling the New Zealand regime on the Australian regime, and that compliance with the Australian TGA regime should satisfy the New Zealand regulatory regime.

The vast majority of the sunscreen sold in the New Zealand market is already manufactured to meet the requirements of the Australian TGA regulatory regime (including Cancer Society sunscreen). Accordingly, we believe the costs to industry and consumers from this change (when considered across the entire sunscreen market) is minimal.

Whānau/people with cancer are vulnerable to therapeutic product claims

Cancer Society supports having a regulatory framework that includes Natural Health Products. The current consumer protection regulatory regime overseen by the Commerce Commission does not provide sufficient protection for New Zealanders in this case. We have seen some patients misled or confused by claims of a therapeutic nature on natural health products.

Information about cancer

The Cancer Society provides information on a wide array of cancer-related topics, the aim being to provide factual, helpful information to whānau and others in a variety of formats. The Cancer Society does not promote one approach over another, as it is the affected person's right to make an informed choice.

We have some concern regarding the proposed change in definition and approach to advertisement. We see a difference between advertising and communicating information. The Act should focus on advertising i.e. activities which 'promote' one course of action over another.

It would be a concern if factual information about treatments published by cancer support groups met the new threshold of advertisements. The Society asks for further consideration of the definition of advertisements to ensure that factual information provided to whānau with cancer by cancer support organisations is not considered an advertisement.

Personal importation of medicines not available in Aotearoa/ New Zealand

The Society is concerned that the proposed process for personal importation of medicines not available in Aotearoa/New Zealand will be expensive, bureaucratic and lengthy. For some, personal importation is a lifeline – for example, pazopanib for people with soft tissue sarcoma.

A pharmacist can request a permit to import unauthorised medicines for an individual patient who has received a prescription, but this will presumably incur additional costs for the pharmacist (and therefore the patient), take time when time and money might be short, and for rarer drugs, it may be difficult to find a pharmacist willing to arrange this.

The Cancer Society recommends that for whānau with cancer, the process of both self-importation and named patient supply is clear, readily accessible, timely and at minimal cost to the person with cancer.

Currently the willingness of pharmacies and wholesalers to source and supply the medicines currently personally imported is unknown. Additionally some of the medicines currently personally imported may come from questionable sources that regulated channels are not be willing to use. The requirement for a sourcing exercise (rather than someone ordering the medicine themselves) could delay access to the medicine in these situations. For some unapproved medicines, it may be necessary for the wholesaler to maintain a small stockpile of the medicine so it is available for immediate release once a special clinical needs supply authority had been issued. If so, their wholesale licence should authorise such stockpiling. This might be used, for example, for life-saving cancer treatments. The Cancer Society recommends that this ability to maintain a small stockpile of the medicine so it is available for immediate release once a special clinical needs supply authority has been issued is progressed.

Use of cell and tissue therapeutic products

The Bill proposes changes to regulation of cell therapies, impacting stem cell transplants (including stem cells for transplantation, virus-specific T-cells, CAR T-cells etc). As cell products are typically 'unregistered' by Medsafe, but in the new environment may now require a pharmacist to import them. We recommend special consideration is given to the regulation of CAR T-cell treatment to ensure that the regulatory regime supports this life saving treatment quickly becoming available in New Zealand following the clinical trials stage. The curative potential of this treatment for many with cancer should not be hindered by the regulatory regime.

Recommendations

1. The Cancer Society supports introduction of a regulatory framework able to consider the safety and quality of natural health products (NHP) across their life cycle.
2. The Cancer Society recommends that -
   a. an exemption mechanism or an abbreviated regulatory process is provided for clinical trials that involve treatment of a small number of people (e.g. < 50 NZ patients/year) with life-threatening conditions (such as advanced cancers), particularly where the medicines involved have already been through an assessment by competent authorities (e.g. in Australia, Europe, USA), and
   b. the new regulator provides fee exemptions for public good clinical trials (e.g. co-operative group trials or those funded by the Health Research Council or Cancer Society), as opposed to trials run principally for the benefit of a pharmaceutical company
   c. support the purpose of this Bill.
3. The Cancer Society asks for further detail on the definition of advertisements to exclude factural information provided to whānau by charitable support agencies
4. The Cancer Society recommends that access to and use of rongoā Māori is not impacted by increased compliance costs and/or controls on ingredients.
5. The Cancer Society recommends that for whānau with cancer, self importation and named patient supply of cancer medicines not available in Aotearoa/New Zealand is clear, readily accessible, timely and at minimal cost to the person with cancer.
6. The Cancer Society recommends that the ability for a pharmacist or wholesaler to maintain a small stockpile of a medicine, so it is available for immediate release once a special clinical needs supply authority has been issued is progressed.
7. The Cancer Society recommends special consideration is given to the regulation of CAR T-cell treatment to ensure that the regulatory regime supports this life saving treatment quickly becoming available in New Zealand following the clinical trial.

Thank you for the opportunity to make this submission.

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New Zealand Cancer Society

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