BCAC submission on the proposed Therapeutic Products Bill (TPB)

The Breast Cancer Aotearoa Coalition (BCAC) is a charitable incorporated society. Our membership spans over 30 breast cancer charities and groups across Aotearoa, as well as individual members. Our purposes, as a patient-based organisation, are to support, inform and represent those diagnosed with breast cancer in Aotearoa from an evidence basis.

We have grave concerns about the potential impacts of the Therapeutic Products Bill (TPB) as currently drafted. Enactment of the TPB could result in adverse consequences for our members and others diagnosed with breast cancer in Aotearoa, as well as many other New Zealanders with various health conditions.

Issues with the Proposed Therapeutic Products Bill

BCAC has concerns in three main areas:

1. Importation of Unregistered Medicines
2. Definition of "Advertising" of Unregistered Medicines
3. Clinical Trials – Access and time limits for approval

1. Importation of Unregistered Medicines

Currently, under the Medicines Act, (Section 29), private imports of medicines are permitted, as is importation of medicines that are not registered in New Zealand. The Therapeutic Products Bill (TPB) proposes major changes that will make access to unregistered medicines much more difficult for New Zealand patients. This is of significant concern to our members.

We believe that patients should be able to access medicines that are not registered in New Zealand, particularly where these medicines may be life extending or have a significant impact on the quality of life for the patients concerned. These medicines may well be proven effective and registered elsewhere, but not registered by MEDSAFE. They may be undergoing assessment by MEDSAFE. Many companies are now choosing not to register medicines in New Zealand because of the uncertainty of funding created by PHARMAC and the limited budgetary allocation for medicines. Many unregistered cancer medicines are currently provided to patients under Section 29 of the Medicines Act. Furthermore, such medicines are often for patients with rare subtypes of cancer and other rare diseases, whereby companies are loathe to undertake registration processes for such a small market. Suppliers of medicines would be deterred from providing compassionate access to medicines for patients in desperate need. The TPB as drafted would result in New Zealand patients missing out on access to important medicines that are critical to their survival and quality of life.

There will also be situations where the medicine concerned is registered in New Zealand, but the registered product cannot be supplied. Current legislation does enable an (unregistered) alternative to be imported to ensure continuity of supply from a different manufacturer.

Under the proposed legislation, (Section 60), importers will have to be specially licensed to import medicines. A licence or permit would be required prior to supply of a particular unregistered medicine in advance of doing so (Sections 155 and 160 of the TPB). Obtaining a license could well be time consuming and cost-prohibitive, leading to a significant barrier to patients being able to access much needed vital medicines in a timely manner. Without more information about the licensing process and fees, it seems that this will create a barrier in terms of bureaucracy and cost that will prevent New Zealand patients getting necessary access to essential medicines.

The "Special Case Requirement" proposed in the TPB (Section 65) would be unnecessarily burdensome for health practitioners who are already under immense time pressure. In the experience of many New Zealanders diagnosed with breast cancer, our health providers barely have time to fully explain and discuss our diagnosis and treatment options along with their benefits, risks and side effects. They are unlikely to find the additional time needed to fill in the paperwork needed to establish "special cases" for all those needing unregistered medicines. This mechanism would not replace the options currently available under Section 29.

The TPB also makes importation of medicines for personal use more difficult (Section 105).

We ask that the TPB be redrafted to provide a replacement for Section 29 of the Medicines Act to provide legal exemption allowing supply of unregistered medicines by wholesalers and pharmacies if requested or prescribed by a registered medical professional for a named patient. The bill should be written to improve rather than restrict our ability to access medicines.

2. Definition of "Advertising" of Unregistered Medicines

Under the draft TPB, advertising of unregistered products will be illegal and the definition of "advertisement" in the Bill is far too broad. It covers any communication that could be deemed to promote any unregistered product. This would include advocacy by patient groups for new medicines, conference presentations about clinical trial results where a new medicine shows benefit, treatment guidelines, even journal publications, media articles and "Give A Little" pages.

This clause would result in organisations such as BCAC being effectively gagged and our spokespeople potentially thrown in jail or fined for even talking about an unregistered product. This is completely inappropriate as it precludes dissemination of scientific information (for example at international conferences held in New Zealand or in local medical publications) and prevents open discussion about potentially useful medicines. In the modern age where misinformation is rife, it would seem illogical and potentially harmful to prevent scientifically based information from credible sources being disseminated, by defining it as "advertising".

3. Clinical Trials – Access and time limits for approval

The bill proposes to make some changes to the regulation framework for clinical trials. The current framework, whilst not perfect, does allow some international clinical trials to be made available to New Zealand patients. For many patients, this is the best way for them to have access to the most up-to-date therapies being developed internationally. The proposed legislation contains no timeframe for a response to applications for approval of clinical trials (currently 45 days under the HRC's SCOTT committee process, Section 30 of the Medicines Act). This is a retrograde step for patients in New Zealand as it creates uncertainty for multinational trials that will deter international collaborators from undertaking clinical trials in New Zealand. We should be aiming to increase New Zealand's participation in international clinical trials, not making it even more difficult. There are initiatives under way within Manatū Hauora to improve access to clinical trials but if enacted as drafted, the TPB would create additional barriers to trial access.