Medicines Amendment Bill: Government Bill 134-1

Abstract

Breast Cancer Aotearoa Coalition* (BCAC) supports the intent of the Medicines Amendment Bill. We have outlined best-practice medicine regimens for breast cancer and assessed their registration status in New Zealand. Of 13 identified breast cancer medicines requiring registration, 11 are registered in at least two recognised international jurisdictions. We acknowledge the critical role pharmaceutical companies play in initiating applications for both registration and funding of medicines. While we welcome and support efforts to reform Medsafe's registration process, we are of the view this is one step on the improvement path. To truly accelerate access to medicines, Pharmac's processes must also be streamlined, and its funding increased. To highlight this issue, we have provided information on breast cancer medicines that remain unfunded or unregistered in New Zealand. In addition to the improvements made to Medsafe's registration processes reforms are needed to Pharmac's processes as outlined in Honourable David Seymour's Letter of Expectations, with the goal of faster access to medicines to improve patient outcomes. *Who we are is detailed at the end of our submission.

The Medicines Amendment Bill, Government Bill 134—1

The Medicines Amendment Bill (the Bill) proposes to improve access to medications. It does so by amending the Medicines Act 1981 through introduction of a verification pathway under which medicines could be approved for distribution in New Zealand, if they have been approved by two recognised overseas jurisdictions. This would enable approval for medicines to be expedited, and medicines may be available for New Zealanders more quickly. It is this aspect of the Bill, Breast Cancer Aotearoa Coalition wishes to comment on.

Our submission

Breast Cancer Aotearoa Coalition (BCAC) has written this submission to:

- Support the intent of the Bill that should a medicine already have approval from two recognised agencies, then requiring a detailed and lengthy Medsafe approval process does not significantly improve a medicine's safety, it does create delays.
- We also submit that the path to registration and subsequent funding of medicines must be made easier to remove barriers to pharmaceutical companies making applications to Medsafe. In the case of breast cancer, there are 13 medicines recommended in international guidelines and best practice regimens, funded in similar countries. Yet companies have not been motivated to register their medicines (Table 1 below) and only one medication may today benefit from the verification process, while the other 12 would require an application to be made.
- We additionally submit that Pharmac's funding processes and access to funding is impacting pharmaceutical company perceptions of our regulatory market, with long time frames, lack of transparency discouraging them from bringing medicines to the New Zealand market. These also deserve to be simplified in similar fashion and better funded, to truly expedite access to therapies.

Our support for a Medsafe verification process

In making this submission we acknowledge that global regulatory agencies [1,2,3] such as

- the European Medicines Agency with approximately nine hundred employees and over forty authorities from across EU member states and
- the UK's Medicines and Healthcare products Regulatory Agency with over a thousand employees and
- The US Food and Drug Administration (FDA) now with 14,000 employees and *other similar agencies* ***can be relied on to make strong evidence-based decisions on the safety and efficacy of medicines***.

We also agree with and support the suggestion within the Bill that Medsafe with approximately 60 staff should not seek to replicate these larger agencies' processes. They should provide a streamlined medicines approval process to speed up public access to approved medicines. This can be achieved by introducing a verification pathway under which medicines are approved for distribution in New Zealand, when they have been approved by 2 recognised overseas jurisdictions.

This will mean that medicines can be made available as approved medicines for some New Zealanders more quickly and efficiently should pharmaceutical companies choose to introduce a medicine to New Zealand.

We accept that detailed requirements of this pathway will be set out in secondary legislation (the **Rules**).

There are critical dependencies impacting the speed of access

1. The role of pharmaceutical companies

In making our submission we note that the speed of supply of medicines to New Zealand is not only dictated by Medsafe's process but also by other supply chain and commercial factors. Currently, the decision to initiate registration lies solely with pharmaceutical companies and not Medsafe itself or other stakeholders. **We submit that where access has been granted by two recognised jurisdictions, other stakeholders should be able to initiate registration.**

We are also very aware that some pharmaceutical companies are slow and reluctant to initiate registration in New Zealand for a variety of reasons. To assist the Health Select Committee we have provided an understanding of the potential impact that introduction of the proposed verification system may have for breast cancer. Table 1 below shows that for advanced breast cancer, across the three breast cancer subtypes (HR+, HER2+ and TNBC) ***thirteen*** medicines have been identified from breast cancer best practice regimens/guidelines. Of these thirteen medicines, only 1 has a current Medsafe application in progress. This medicine is Roche's, inavolisib, which appears to be registered through just one recognised jurisdiction (FDA), the other is China's NMPA, although we understand EMA registration is pending. ***Eleven*** of the thirteen are registered in two recognised jurisdictions and would meet the Bill's fast track verification process requirements. None of those have live Medsafe applications. Within the current legislation, pharmaceutical companies have a sole and critical role in initiating registration.

Table 1: Breast cancer medicines that remain unregistered in NZ that are registered in similar jurisdictions globally

STAGE, SUB-TYPE AND SUBGROUP	NZ UNREGISTERED MEDICINES	GLOBAL REGISTERED APPROVALS
Early HR+		
Advanced HR+	sacituzumab govitecan (Trodelvy®)[2] capivasertib (Truqap®)[1*] inavolisib (Itovebi®) ✓ elacestrant (Orserdu®) and everolimus (Afinitor®)[1]	AU 2022, FDA April 2021 EMA June 24, FDA Nov 2023 FDA Jan 2023, NMPA (China) March 2025 FDA Jan 2023, NICE Dec 2024 FDA March 2009, EMA Nov 2024
HER2 ultra-low subgroup:	trastuzumab deruxtecan ((Enhertu®)	FDA Jan 2025, EMA April 2025
Early HER2+		
Advanced HER2+	neratinib (Nerlynx®) margetuximab (Margenza®)	FDA Oct 23, AU March 2019 FDA March 2020, NMPA (China) Aug 2023
HER2 ultra-low subgroup	trastuzumab deruxtecan (Enhertu®)	FDA Jan 2025, EMA April 2025
Early TNBC	talazaporib (Talzenna®)	EMA April 2019, FDA Jul 2023
Advanced TNBC	sacituzumab govitecan (Trodelvy®)[1,2] talazaporib (Talzenna®)	AU 2022, FDA April 2021 EMA April 2019, FDA Jul 2023
HER2 ultra-low subgroup	trastuzumab deruxtecan (Enhertu®)[1,2]	FDA Jan 2025, EMA April 2025

✓ An application for registration has been made by one pharmaceutical company for unregistered breast cancer medicines in New Zealand. This medicine is registered by 1 recognised overseas jurisdiction (FDA) and would need to wait for the pending FMA registration as the NMPA registration is not in the recognised list.11 of the 13 listed are registered in two recognised jurisdictions but all require pharmaceutical company initiation of an application.

Table 1 is detailed further in Appendix 1.

BCAC is therefore hopeful:

- Pharmaceutical companies will prioritise the supply of medicines to the New Zealand market alongside other competing market opportunities if the bill passes into law.
- Global decision makers will view the New Zealand regulatory market with less caution.
- Pharmaceutical companies will choose to put more time, effort and resources towards New Zealand if Pharmac improves its reputation for slow, non-transparent and difficult funding approvals.

BCAC frequently advocates to pharmaceutical companies for the registration of medicines and is disappointed in the low level of engagement in the New Zealand market, demonstrating the importance of the intent of the Bill. We recognise and wish to emphasise that a lengthy process replicating what has been competently undertaken elsewhere creates unnecessary delay in the medicine access supply chain and the proposed Bill should expedite this process. We are hopeful that this improved process may encourage greater pharmaceutical company participation in the New Zealand market.

2. Impact of Pharmac's processes on the medicine registration process.

Removal of a delay in access through Medsafe's processes is just one of the necessary steps in improving speed of access to medicines. The current medicines funding deficit in New Zealand compared with similar countries will continue to increase unless Pharmac's processes are also reformed. There is an ongoing need to also improve both Pharmac's processes and level of funding.

We remain hopeful, however, that a faster Medsafe registration process, may increase the likelihood that pharmaceutical companies will participate in the New Zealand market.

Below we highlight the current medicine gap for best practice breast cancer medicines, for both unregistered and unfunded products.

Table 2: Funding and registration status of breast cancer medicines in NZ

STAGE, SUB-TYPE AND SUBGROUP	NZ UNREGISTERED MEDICINES	NZ UNFUNDED MEDICINES
Early HR+		abemaciclib (Verzenio®)[1,2] ribociclib (Kisqali®) olaparib (Lynparza®)
Advanced HR+	sacituzumab govitecan (Trodelvy®)[2] capivasertib (Truqap®)[1*] inavolisib (Itovebi®) elacestrant (Orserdu®) and everolimus (Afinitor®)[1]	sacituzumab govitecan (Trodelvy®)[2] abemaciclib (Verzenio®)[1,2] capivasertib (Truqap®)[1*] alpelisib (Piqray®) elacestrant (Orserdu®) enviroximes (Afinitor®)[1]
HER2 low and ultra-low subgroup:	trastuzumab deruxtecan ((Enhertu®)	trastuzumab deruxtecan ((Enhertu®)
Early HER2+		trastuzumab sub-cutaneous (Herceptin SC®)[1], neratinib (Nerlynx®) pertuzumab (Perjeta®)[1*,2], trastuz + pertuz SC (Phesgo®)
Advanced HER2+	neratinib (Nerlynx®) margetuximab (Margenza®)	Herceptin SC[1] Phesgo®, trastuzumab (Herzuma®) (retreatment)[1] lapatinib (Tykerb®)[1,2] neratinib (Nerlynx®) tucatinib (Tukysa®)[2] margetuximab (Margenza®)
HER2 low and ultra-low subgroup	trastuzumab deruxtecan (Enhertu®)	trastuzumab deruxtecan (Enhertu®)
Early TNBC	talazaporib (Talzenna®)	pembrolizumab (Keytruda®)[1,2] olaparib (Lynparza®)
Advanced TNBC	sacituzumab govitecan (Trodelvy®)[1,2] talazaporib (Talzenna®)	atezolizumab (Tecentriq®) sacituzumab govitecan (Trodelvy®)[1,2] talazoparib (Talzenna®) olaparib (Lynparza®)
HER2 low and ultra-low subgroup	trastuzumab deruxtecan (Enhertu®)[1,2]	trastuzumab deruxtecan (Enhertu®)[1,2]
Various sub-types		nab-paclitaxel (Abraxane®)[1] , eribulin (Halaven®)[1], denosumab (Xgeva®/Prolia®)[1] bevacizumab (Avastin®)[1]

Key: **1** Funded in Australia (16 indications), **1*** PBAC recommendation for PBS funding in Australia i.e. soon to be funded (2 indications (*capivasertib and pertuzumab*)). **2** ESMO MCBS score of A for early breast cancer; 4 or 5 for advanced breast cancer (12 indications). Breast cancer has a backlog of approximately 32 unfunded medicines, 11 with an ESMO MCBS score of A[2], for early breast cancer; 4 or 5 for advanced breast cancer (12 indications) with 13 unregistered medicines.
Table 2 is detailed further in Appendix 1.

Breast cancer medicine registration and funding in context.

Each year around 3,550 New Zealanders (and an additional 450 with ductal carcinoma in situ) are diagnosed with breast cancer. 95% survive 10 years if their cancer is detected by screening and 85% if their breast cancer is discovered symptomatically [4,5.] However, **20-30% of all breast cancers eventually return or become advanced**, mostly due to delayed later-stage diagnosis [6]. Breast Cancer is the biggest cause of death for New Zealand women under 65 years of age [7] . It is also one of the most commonly diagnosed cancers in our country [8].

In 2018, the median survival for New Zealand advanced breast cancer patients was just 16 months compared to 32+ months globally. Updated (2024) data shows median survival length has improved only slightly for New Zealand patients to 18 months [8]. In other countries survival can be twice as long. Advanced breast cancer patients are heavily reliant on access to therapies to stall the progression of their disease or to improve overall survival. These lamentable statistics indicate that relative to other jurisdictions we are not doing well enough. The major factor in poor cancer survival rates is limited access to modern medicines [8]. Therapies today are more precise and biomarker directed. Not all patients are treated in the same way with the aim being to transform cancer from a terminal disease to a chronic condition. Advanced breast cancer patients today may even reach a status of no evidence of disease or may bravely be described as "cured" if they are treated early, well and on a timely basis. "My perception is we've increased long-term responders with HER2-positive metastatic breast cancer from 16% in CLEOPATRA in 2020 to around a quarter of patients taking trastuzumab deruxtecan in 2023." says Paul Tarantino, Dana Faber Institute, Boston [9].
aiming to transform cancer from a deadly disease to a chronic one

The question being asked is whether the HER2 treatment landscape can be replicated in other subtypes of breast cancer and/or in metastatic tumours originating from other organs? With access to these modern therapies, we are beginning to revise our perception of metastatic cancer, from it being a terminal illness with a limited life expectancy to a chronic condition with the potential for a cure.

The additional funding for medicines announced by the Government in June 2024 was extremely positive. However, New Zealand still remains behind much of the OECD in accessing standard of-care treatments with significant downstream effects on our society, and the economy. New Zealand's public funding of modern medicines lags behind comparable countries and ranks last for market access to modern medicines UK 96%, Finland 70%, Australia 49% and New Zealand 17% [8]. New Zealand remains at the bottom of the OECD for medicines funding. On average, applications for funding have been with Pharmac for 6 years [8]. Until New Zealand moves closer to the OECD average for medicines investment, from 0.4% of GDP to 1.4% GDP OECD average, the full benefits of the Bills intent cannot be achieved [8].

Breast cancer has three main subtypes and therapeutic approaches.

The majority of breast cancer patients diagnosed each year have the HR+ (70%) subtype, approximately 20% HER2+ subtype and 10-15% Triple Negative breast cancer (TNBC). All three have different medicine regimens, approaches to treatment, risks and prognoses and increasingly there are growing subgroups (e.g., HER2low and ultra-low) across and within subtypes for example trastuzumab deruxtecan a new breakthrough therapy. There are also extensions to existing indications for example olaparib funded in other jurisdictions for early and advanced breast cancer for those with a hereditary germline BRCA1/2 pathogenic variant can be expected to be extended to germline PALB2 (Pal of BRCA1/2) a related pathogenic variant and also somatic (tumour) BRCA1/2mutation. These subgroups and extensions all currently require the full Medsafe process. For example, trastuzumab deruxtecan a recent break through treatment initially registered and funded in New Zealand for HER2+ disease also shows significant benefit for those with HER2 low and ultra-low subgroups across HR+ and TNBC. This has meant that separate Medsafe applications must be made for HER2+, HER2 low and now HER2 ultra-low. Each application can take a year or more. Table 1 shows that HER2 low and HER2 ultra-low are now registered in two relevant jurisdictions. There is still no application from AstraZeneca for HER2 ultra-low. This medicine and its use would be a prime candidate for a fast-tracked verification process once AstraZeneca applies or for a fast-tracked application by another stakeholder.

Conclusion

Breast Cancer Aotearoa Coalition (BCAC) supports the intent of the Medicines Amendment Bill. We have outlined best-practice medicine regimens for breast cancer above and assessed their registration status in New Zealand. Of 13 identified breast cancer medicines requiring registration, 11 are registered in at least two recognised international jurisdictions. We acknowledge the critical role pharmaceutical companies play in initiating applications for both registration and funding of medicines.

While we welcome and support efforts to reform Medsafe's registration process, we are of the view this is one step on the improvement path. To truly accelerate access to medicines, Pharmac's processes must also be streamlined, and its funding increased.

Who we are

The Breast Cancer Aotearoa Coalition (BCAC) is a patient-based incorporated society and registered charity that aims to make world-class detection, treatment and care accessible to everyone affected by breast cancer in New Zealand. We provide support and information to empower those with breast cancer to make informed choices about their treatment and care and provide a voice for those who have experienced breast cancer. BCAC has over 30 member groups from across New Zealand with a number of these represented on our committee.

References

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Appendix 1. Summary of Table 1 and 2 (unregistered and unfunded medicines by subtype).

Utilising best practice breast cancer regimens by subtype we have shown that New Zealand has a number of unregistered and unfunded medicines, (***Table 1 and 2)*** summarised for the Health Select Committees benefit**.**

Subtype: HR+ Breast Cancer

For early HR+ breast cancer there are no outstanding Medsafe applications but there are three medicines awaiting approval abemiciclib, ribociclib and olaparib. For advanced HR+ breast cancer there are **six unregistered medicines**, all but one requiring a pharmaceutical company to initiate the process and, seven registered but unfunded medicines.

Subtype: HER2+ Breast Cancer

For early HER2+ breast cancer there are no medicines awaiting registration but four medicines awaiting funding, two of which can be rapidly delivered subcutaneously, reducing time needed in infusion chairs and reducing health system infrastructure needs and resource costs and patient travel and infusion time. For advanced HER2+ breast cancer there are **three unregistered medicines**: trastuzumab deruxtecan for HER2 ultra-low, neratinib, margetuximab and three registered but unfunded medicines. The HER2+ subtype would benefit from funding of trastuzumab deruxtecan (HER2low and ultra-low), trastuzumab retreatment a standard of care in most countries and access to tucatinib (registered but not yet available for supply in New Zealand from Pfizer).

Subtype: TNBC

This regimen is considered the most aggressive subtype impacting younger people. Medsafe registration is **needed for one early TNBC** therapy and **three advanced TNBC therapies** and there are several important medicines awaiting funding. These include olparib, sacituzumab govitecan, trastuzumab deruxtecan for HER2 low and ultra-low and pembrolizumab for early TNBC breast cancer.

Note: The breast cancer landscape changes over time. The information detailed in this submission has been gathered between December 2024 and May 2025. It provides a snapshot over that period but will be subject to change over time.