MANATŪ HAUORA
MINISTRY OF HEALTH

Briefing

Therapeutic Products Bill – Personal importation of medicines and advertising

Date due to MO:	14 April 2023	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	HR2023023520
To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Therapeutic Products Bill – Personal importation of medicines and advertising

Security level:	IN CONFIDENCE	**Date:**	14 April 2023
To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. On 11 April 2023 you requested advice about how the personal importation of medicines was going to be addressed in the Bill, following the issue having been raised by a number of parties at the oral hearings held by the Health Committee.

2. The report also clarifies the rationale for the new advertising provisions contained in the Bill and how they are expected to operate in practice.

3. In response to your query, this briefing sets out:

   - relevant clauses in the Bill
   - concerns raised by submitters in relation to both issues
   - the current position in the Bill (and rationale) in relation to both issues
   - the proposed amendments recommended by the Ministry in the Departmental Report that respond to concerns raised by submitters.

Summary

4. While the Ministry considers that the Bill provides a flexible regime to enable the importation and supply of lifesaving, unauthorised medicines, it has proposed some amendments in the Departmental Report to give greater certainty to health practitioners and the public. Likewise, for the provisions relating to advertising.

5. In relation to personal importation of prescription medicines, the Ministry is recommending in the Departmental Report:

   a. Amending clause 65 to broaden the scope of matters a health practitioner prescriber can consider before prescribing and importing an unauthorised medicine, for example that the cost of an authorised medicine available in New Zealand is unaffordable for the patient. This detail would be set out in secondary legislation.

   b. Amending clause 105 to remove the blanket prohibition on personally importing prescription medicines. We are recommending retaining limits on the amount of a medicine that can be personally imported and recommending that a health practitioner has issued a prescription for the medicine.

6. The Departmental Report also proposes minor amendments to the advertising provisions in the Bill to mitigate the risk of unintended consequences including:

a. Minor amendments to clause 193 and 194 to clarify that a 'communication' that is exempted under the regulations can be one that involves unauthorised therapeutic products

b. Enabling regulations made under clause 193(3)(f) or 194(g) to require a person to disclose funding or in-kind support received from the sponsor, manufacturer or supplier of the therapeutic product the subject of the advertisement

c. Creating a defence to the offence of unlawful advertising for conduct engaged in good faith for the purpose of satire, research, study, criticism or review, reporting the news, advocacy, protest and industrial action, public discussion or to advocate for a change to law or Government policy.

7. The Ministry considers that these amendments to the Bill address the concerns raised by submitters, while balancing the Government objectives of mitigating the risks of counterfeit and contaminated medicines and mitigating the adverse impacts of certain advertising practices on patient health and policies relating to funded medicines.

8. The Departmental report was provided to the Health Committee on 13 April 2023 and will be considered on 17 April 2023.

Recommendations

We recommend you:

a) **Note** that the Ministry has responded to submissions on the Bill by proposing amendments in the Departmental Report to: **Noted**

- Increase the ability for individuals to personally import lifesaving prescription medicines
- Give greater discretion to health practitioner prescribers to prescribe unauthorised medicines to meet their patient's clinical needs
- Address unintended consequences relating to the Bill's current advertising provisions.

b) **Note** that the detail of the advertising exemptions will be set out in secondary legislation to enable nuanced controls that are necessary to respond to the challenges of advertising via social media and astroturfing campaigns. **Noted**

Steve Waldegrave
Associate Deputy Director-General
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Date: 14 April 2023

Hon Dr Ayesha Verrall
Minister of Health
Date: 21/4/23

Therapeutic Products Bill – Personal importation of medicines and advertising

Background

9. On 11 April 2023 you requested advice about how the personal importation of medicines was going to be addressed in the Therapeutic Products Bill (the Bill), following the issue having been raised by a number of parties at the oral hearings held by the Health Committee.

10. There are two main reasons people may want to personally import life-saving medicines. First, if there is a no suitable product available in New Zealand that has been approved by Medsafe. Second, there may be an approved product available in New Zealand but it is not publicly funded by Pharmac (either for any patient or for the specific patient). As such, media and public attention on this issue often conflates the approval of a medicine (following an assessment of its safety, quality and efficacy) with a separate decision over its funding. Funding for medicines is outside the scope of the Bill.

11. The Departmental Report proposes minor amendments to the Bill to address some of the concerns raised in oral hearings about people being unable to access unauthorised, lifesaving medicines.

12. The Departmental report was provided to the Health Committee on 13 April 2023 and will be considered on 17 April 2023.

Relevant clauses in the Bill

13. As a general principle, clause 67 provides that a therapeutic product must be authorised by the Regulator before it can be imported into, supplied in or exported from New Zealand. A medicine will only be authorised following an independent evaluation by the Regulator of its safety, quality and efficacy. This ensures New Zealanders can be confident that the medicines they need, access and use are not counterfeit or contaminated and achieve their stated purpose.

14. However, recognising that there are some legitimate grounds when unauthorised products need to be imported into New Zealand, the Bill provides multiple pathways for the importation and supply of unauthorised medicines. These include:

    a. Prescription and importation by a health practitioner prescriber (clauses 84, 88)

    b. Licences and permits (Part 5)

    c. Personal importation either in a person's personal luggage or via an online delivery (clause 105). This memo primarily focuses on this pathway.

15. Clause 105 of the Bill (Patient or carer importing medicine for personal use) allows for the importation of medicines that do not have a New Zealand authorisation for personal use. In general, there are few restrictions on importing medicines in a person's personal luggage – other than a 3-month supply limit.

16. There are more controls on arranging for a medicine to be sent from overseas (for example, buying it online from an overseas website). If an online purchase meets all the

criteria in clause 105(4), the person is allowed to import the medicine. If the criteria are not met, the medicine would not be allowed to be imported. Relevantly, this importation pathway cannot be used to import prescription medicines (given the high risks associated with these products).

Concerns about access to personally imported prescription medicines

17. A range of concerns relating to restrictions on the importation of prescription medicines and NHPs for personal use came up in submissions. The most common theme was that if passed, the Bill would reduce or remove access to such imports, with adverse health consequences for patients who rely on these life-saving medicines.

18. Comments primarily focused on clause 105, which would prohibit personal imports of unauthorised prescription medicine by mail or courier (while continuing to allow personal importation in their personal luggage by travellers).

19. Submitters perceived there would be a restricted ability of health practitioners to approve unauthorised medicines, including from overseas sources. Currently, this practise is enabled by section 29 of the Medicines Act. As explained above, this concern is somewhat misplaced, as clauses 84 and 88 (combined with clause 65) provide for a clinical access pathway for unauthorised medicines. However, this pathway requires an order and delivery to be arranged by a health practitioner or a licenced intermediary, which helps ensure the public is not put at risk from counterfeit or otherwise sub-standard medicines.

20. One significant concern expressed was where a medicine is available in New Zealand but it is not funded. In this case, a patient might seek to parallel import another version of the product from a different supplier. These alternative medicines are frequently described as 'generics' even though this may not be the case in reality: for example, the product could be counterfeit or patents might still be in effect in some cases.

Current position in the Bill on importation of prescription medicines

21. The Bill seeks to balance ensuring access to lifesaving medicines (assumed here to be 'prescription medicines') with the need to avoid the harms from unauthorised medicines, which may be counterfeit, contaminated or otherwise not effective for a patient.

22. As currently worded, clause 105 does not permit individuals to order unauthorised prescription medicines over the internet and have them delivered to their place of residence in New Zealand. This is to:

    a. Mitigate the risk of counterfeit, contaminated or otherwise inappropriate medicines being imported into New Zealand and

    b. Retain sufficient incentive for product manufacturers to apply for a New Zealand authorisation for their product. Overseas manufacturers may see less reason to apply for market authorisation if they can supply a product to patients in New Zealand without having its safety, quality and efficacy evaluated by the New Zealand Regulator.

23. Under the Bill, importation and supply of unauthorised prescription medicines can be authorised by the issue of a licence or permit by the Regulator and it is anticipated that some firms may seek to obtain a licence or permit. Requiring importers to be licenced has the following advantages:

a. the Regulator can set appropriate conditions on importers to ensure proper record keeping that enables post-market regulatory actions such as recalls

b. the Regulator could require importers to have appropriate systems in place to mitigate the risks of medicines being sourced from unreliable or disreputable overseas manufacturers or distributors

c. the Regulator can use licence conditions to provide some safeguards on the importation of unauthorised medicines (eg, measures to ensure safe and proper handling, storage and transportation; and to prevent the diversion and abuse of certain medicines)

d. the public and the Regulator have greater transparency on who and how unauthorised products can be brought into the country (as licence and permits holders will be listed in the public Therapeutic Product Register)

e. the Regulator could share guidance and information with importers on emerging risks and safety issues in the global supply chain.

24. In addition, a clinical access pathway in the Bill will allow health practitioners to prescribe necessary medicines (clauses 84 and 88), even if they are unauthorised, but with appropriate oversight to mitigate the risks of contaminated and counterfeit products. This provides a way for individuals and whānau to access affordable medicines from overseas that they already consume, but with some degree of regulatory oversight to address possible quality and safety concerns.

25. Medication that is prescribed and supplied through regular channels also maintains the clinical connection and oversight that mitigates some of the risks associated with importation and use of unauthorised products.[1]

26. Clause 65 is intended to work with professional standards set under the Health Practitioners Competence Assurance (HPCA) Act and secondary legislation made under the Bill. The standards and secondary legislation will provide 'criteria' and other 'requirements' that a practitioner will need to consider. These requirements are intended to help mitigate some of the risks associated with the importation and use of unauthorised products.

Proposed approach in Departmental Report

27. Following submissions and oral hearings, the Ministry has recommended amendments to clause 65 and/or 105 to reduce the impact on individuals seeking to access less expensive medicines from overseas. This is because the Bill is ambiguous as to whether cost to a patient is a relevant consideration under clause 65.

28. In relation to the issue discussed above, the Ministry proposed to amend:

a. clause 65 to broaden the scope of matters a clinician can consider in reaching a conclusion that there is no 'suitable' medicine or medical device available with a New Zealand authorisation that meets the clinical needs of the patient. This could

1 Before prescribing an unauthorised product under this pathway, practitioners must be satisfied that: (1) there is no available medicine or medical device with a NZ authorisation that is suitable to meet the clinical needs of the patient and (2) it is appropriate (eg, clinically) to carry on the activity with the medicine or device that does not have a NZ authorisation (clause 65).

be achieved, for example, through amendments to the power to make 'requirements' or 'criteria' in secondary legislation.

b. clause 105 to remove the complete prohibition on importing prescription medicines as part of the 'delivery conditions' and introduce a requirement that:

   i. the medicine is prescribed by a New Zealand health practitioner prescriber for that medicine consistent with clause 65

   ii. the person importing the medicine is ordinarily resident in New Zealand

   iii. the medicine is not subsequently exported from New Zealand (a consequential amendment to clause 107 will be required).

29. Other restrictions in clause 105 (eg, relating to supply limits and a rule making power for the Regulator) would be retained.

30. The Ministry has also recommended to the Health Committee that, in amending clause 105, safeguards are included to reduce the risk that medicines are purchased from overseas distributors known or suspected by the Regulator of supplying counterfeit or contaminated products.

31. These amendments have also been suggested via the Departmental Report, provided to the Health Committee on 13 April 2023.

Related Issue – advertising provisions

32. The Minister would be aware of recent media coverage of "Give-a-Little" pages raising money for unfunded drugs and the possible impact on such pages, and similar communications, of the new advertising provisions contained in the Bill. For example: https://www.stuff.co.nz/national/health/300851481/calls-for-clarity-over-wording-in-therapeutic-products-bill

33. Clause 193 explains what an advertisement is for a therapeutic product and what it means to distribute it. Regulations can be made to narrow the application of this clause. Clause 194 contains further restrictions on advertising – including a prohibition on advertising unauthorised medicines and clause 253 creates an offence of unlawful advertising.

34. The intention of clause 193 and clause 194 is to prevent promotion of therapeutic products in New Zealand where they do not hold New Zealand authorisation. It is not intended to capture instances where therapeutic products are mentioned but are not promoted.

35. Written and oral submissions received during the Select Committee process also commented on the definition of advertisement, and recommended the activities classified (or not classified) as advertisements be specified.

36. For example, it has been suggested that patient appeals for fundraising, patient advocacy activities and medical education could be excluded from the definition of advertisement. Alternatively, some industry bodies, including Medicines New Zealand, suggested the definition be amended by inserting the words 'for the purpose of sale.' This would result in an approach similar to the one currently contained in the Medicines Act which is linked to the commercial purpose of therapeutic product advertisements. It would avoid inadvertently capturing the provision of information for other purposes like research.

Proposed approach in Departmental Report

37. s 9(2)(g)(i)

38.

39.

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41.

42.

Ends.

Minister's Notes