Briefing

Therapeutic Products Bill: additional information regarding innovation

Date due to MO:	12 May 2023	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2023023237
To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
Tim Vines	Manager, Therapeutics Strategy, Policy and Legislation	s 9(2)(a)
Steve Waldegrave	Associate Deputy Director-General Strategy, Policy and Legislation	s 9(2)(a)

Minister's office to complete:

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☐ See Minister's Notes	☐ Withdrawn	

Comment:

Therapeutic Products Bill: additional information regarding innovation

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To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1 This report responds to your request on 31 March 2023 for a brief description of how the future regulatory regime for therapeutic products will support product innovation, together with examples of the type of product that could be supported by the new regime.

2 This report discloses all relevant information and implications.

Comment

3 On 31 March 2023, you discussed with officials a Ministry for Business, Innovation and Employment (MBIE) briefing which called for more explicit support in the Therapeutic Products Bill (the Bill) for product innovation.

4 You agreed that there was no need to change the Bill, as it already includes provisions that will support product innovation. You also noted the importance of appropriately resourcing the Therapeutic Products Regulator (the Regulator) to support innovative pathways.

5 You asked MBIE and Manatū Hauora officials to provide you with a note containing key messages about how the future regulatory regime for therapeutic products will support product innovation, with some specific examples of products that would be supported by the new regime.

6 A copy of the note you requested is attached at **Appendix 1**. As the Bill's support for innovation is general, and not product specific, we have also included a summary of how the Bill will support the examples listed in **Appendix 1**.

7 If you agree, MBIE will circulate the note to members of the healthtech industry, including Callaghan Innovation and New Zealand Trade and Enterprise.

Providing support for product innovation under the new regulatory regime

8 The Bill has features that support product innovation generally, and enables the industry to influence how the new regime supports innovation for specific product types (eg, through input on secondary legislation that will govern how products are evaluated by the Regulator).

9 Decisions by Government also provide avenues to support innovation. For instance, the Bill enables financial support for product innovation by waiving or refunding fees or levies. Cabinet has yet to agree to fund such support, although it has agreed to the new regulatory scheme being funded through Crown funding and cost recovery s 9(2)(f)(iv) [redacted]

10 At the 31 March meeting, you expressed interest in giving a public commitment to resourcing the Regulator to put in place innovative pathways. While the Bill is before Health Committee, Manatū Hauora recommends that such a statement wait until the Bill returns to the House. However, the elements of the Bill outlined in this memo (including possible funding options) could form the basis for a speech in Parliament – for example at the Bill's second reading.

Recommendations

We recommend that you:

a)	**Note** that on 31 March 2023, you asked MBIE and Manatū Hauora officials to provide you with a note on how the future therapeutics regulatory regime will support product innovation, together with examples of the type of products that could be supported by the new regime.	**Noted**
b)	**Note** the information requested as set out in **Appendix 1.**	**Noted**
c)	**Note** that on 31 March 2023, you agreed that no revisions to the Bill were necessary to better enable innovation.	**Noted**
d)	**Note** that the Bill has provisions that support product innovation generally and enables the industry to influence how the new regime supports innovation for specific product types through the development of secondary legislation.	**Noted**
e)	**Note** previous Government decisions which mean that the Crown can meet the costs of implementing the new regulatory regime, including the systems and capacities necessary for the new Regulator to carry out its mandate to support product innovation.	**Noted**
f)	**Agree** to MBIE circulating the attached note to members of the healthtech industry, including Callaghan Innovation and New Zealand Trade and Enterprise.	**Yes / No**
g)	**Advise** if you would like a statement about support for innovation to be included in your second reading speech, to be prepared in advance of the Bill returning to the House from Health Committee on 14 June 2023.	**Yes / No**

Steve Waldegrave

Associate Deputy Director-General

Strategy, Policy and Legislation

Ministry of Health

Date: 12/05/2023

Hon Dr Ayesha Verrall

Minister of Health

Date: 15/5/23

Appendix 1: How the Therapeutic Products Bill will support product innovation

Innovation must be supported under the new therapeutic products legislation

Clause 4 of the Therapeutic Products Bill (the Bill) mandates support for the "timely availability" of therapeutic products, "open and well-functioning markets" and "innovation, including opportunities for Māori."

How the Bill will support innovation

The Bill will:

- Give innovators greater certainty about the standards and rules that apply to their products, especially medical devices and cell and gene-based therapies, which are not regulated, or not well regulated, under the Medicines Act 1981.
- Create a clearer pathway for clinical trials of medicines and medical devices. Clinical trials can enable earlier access to novel and promising treatments, within a framework that manages the risks to participant safety.
- Support the timely supply of urgently needed products, through provisional market authorisations and – for unauthorised products – the licensing and permit system.
- Support exports of natural health products (NHPs), by providing reassurance about the safety and quality of New Zealand products.
- Better enable alignment with overseas regulators and international best practice in the regulation of innovative products.
- Create opportunities for Māori to use mātauranga Māori in the design and manufacture of new NHPs, medicines and medical devices.
- Enable Māori to exercise greater control over the use of mātauranga Māori in product development. Greater control will come from reinforcing ethical guidelines around the protection of Māori data, via clinical trial licensing requirements.

The industry will have opportunities to influence how the new regulatory regime supports innovation

The industry will be consulted on the secondary legislation to be made under the Bill, and on a Regulatory Strategy that will be developed and published by the Therapeutic Products Regulator. These instruments will play a key role in defining the functions and priorities of the regulatory regime set up under the Bill. Consultation will enable the industry to contribute to the design of an approach that supports innovation. Consultation is likely to take place in the 2024/2025 financial year.

The Government will also ensure that innovation is supported

The Government has a number of mechanisms for ensuring that the Bill supports innovation:

- Regulations under the Bill are made on the recommendation of the Minister of Health. This enables the Minister to ensure that support for innovation is factored into the rules which drive the day-to-day work of the Regulator.
- The Minister of Health can give general policy directions to the Regulator.
- Accountability mechanisms built into the Bill:
    - The Regulator is accountable to the chief executive of Manatū Hauora for the performance of their functions and exercise of their powers
    - The Regulator must review the Regulatory Strategy every three years
    - The Minister of Health must review the policy and operation of the Bill every five years.

The Crown will fully meet the costs of designing and setting up the new regulatory function to ensure that it carries out its mandate to support product innovation

By the time the Bill comes into force, the Regulator will need to have in place the skills and knowledge to support innovative products and devices, together with the systems required to provide such support. The Crown will fully meet the costs of designing and setting up the new regulatory function to ensure that it carries out its mandate to support product innovation.

Financial support for product innovation may be available

- Financial support may be available to product innovators under the Bill through assistance with fees or levies.
    - An example of how support could be provided is the assistance option currently operated by Medsafe, where a waiver or refund may be granted if this is in the interests of public health in New Zealand. For instance, a fee waiver currently may be available on a case-by-case basis for clinical trials, or for specific types of bioequivalence studies utilising new generic medicines.
- Under the new regime, some Crown funding will be available to support the development and supply of therapeutic products.
- Decisions about the amount of funding, the process for allocating available Crown funding and where to target funding support will need to be made in advance of the Bill coming into force in 2026. Given the mandate in the Bill, product innovation is a candidate for assistance in the form of Crown funding.

COVID-19 showed that a well-designed regulatory system can assist New Zealand to deploy innovative technologies to deal with health emergencies

One of the important lessons from our experience with COVID-19 is the importance of having regulations that support the evaluation, testing and timely deployment of emerging health technologies. We also learned that there is scope to improve the flexibility and responsiveness of our regulatory system. This has been demonstrated, for example, by the ongoing work to find a viable way of regulating COVID-19 Point-of-Care Test products and practices.

The Bill will enhance the ability of our regulatory system to deploy innovative technologies to deal with health emergencies. It will do so through support for the timely supply of urgently needed products, as well as by creating pathways for innovative products that are clear, straightforward and easily navigated.

The kinds of innovative product that will be supported by the Bill

Products already in NZ which are inadequately regulated. These include medical devices and software as a medical device (SaMDs). More complex products in this category include diagnostic software, robotic surgery machines, and implantable devices such as pacemakers. Tongue depressors and bandages are examples of less complex medical devices.

Products at the early stage of research and development, in New Zealand or overseas – examples of such products which are at this stage, or have been recently, are set out in Table one below.

Table one: Examples of innovative products that will be supported by the Bill

Product *(Likely Bill category)*	Description
Smart Pill *(Medical device)*	Contains a tiny sensor that can communicate with a wearable device to monitor the patient's medication adherence and health status. It can help patients manage chronic conditions and allow doctors to monitor treatment progress remotely.
Artificial Retina *(Medical device)*	A device that is implanted in the eye to restore sight to people with certain types of blindness. It consists of a tiny camera and a microchip that converts light into electrical signals that can be sent to the brain.
Wireless Brain Sensors *(Medical device)*	Implantable devices that can monitor brain activity in real-time. They can help doctors diagnose and treat neurological conditions such as epilepsy, Parkinson's disease and depression.
Wireless Heart Monitor *(Medical device)*	A small device that can be worn on the chest to monitor heart activity. It can detect irregular heartbeats and alert doctors to potential heart problems before they become serious.
Digital Health Apps *(SaMD, but see **Note**)*	Mobile applications that help people manage their health by tracking their fitness, diet, sleep and other health-related data. These apps can help people stay healthy, prevent chronic diseases and manage existing conditions. **Note**: not all digital apps with a health-related function would come within the scope of the Bill.
CRISPR-Cas9 *(Biologic medicine)*	CRISPR-Cas9 is a technology that enables geneticists and medical researchers to edit parts of the genome by removing, adding or altering sections of the DNA sequence. It has recently been developed to improve gene targeting. CRISPR-Cas9 is known to have a lot of potential as a tool for treating a range of medical conditions that have a genetic component, including cancer, hepatitis B or even high cholesterol.
CAR-T-cell therapy *(Biologic medicine)*	A way to get immune cells to fight cancer by changing them so they can find and destroy cancer cells. Sometimes described as a type of cell-based gene therapy, because it involves altering the genes inside T-cells to help them attack the cancer.
mRNA technology *(Biologic medicine)*	A gene-based therapy that uses mRNA is a vaccine or therapeutic agent. The most recent discovery in the mRNA world includes the use of an artificial intelligence tool that optimises the gene sequences for greater potency and stability.
Biological therapeutic products *(Biologic medicine or device)*	Examples are faecal microbiota, hookworms, leeches. Products have various health applications, either potential or proven.

For the types of products listed in the table above:

- The Bill enables an efficient and modern approach to regulating medical devices.
- The Bill will provide more clarity over the regulatory pathway for the product.
- Clear principles in the Bill will ensure that the regime and Regulator support timely availability of products and innovation.
- A new definition of clinical trials will align New Zealand with international best practice.
- An up-to-date, flexible definition of SaMD will enable secondary legislation to adopt good international practice and to respond to developments in this rapidly evolving field.
- A new definition of biologics will ensure fit-for-purpose regulation of biologic medicines (eg, gene therapies) and availability of these important treatments.
- The Regulator will be able to use secondary legislation to provide greater clarity over how combination products are to be regulated.
- More flexible provisions regarding how people in the supply chain can work "under supervision" will support telemedicine and other remote service delivery methods.

Likely categories for individual products are included in the table, but the final decision on categorisation rests with the Therapeutic Products Regulator.