Briefing for decision

Extension of expiry date for specified biotechnical procedures- Xenotransplantation

Date due to MO:	28 February 2025	**Action required by:**	14 March 2025
Security level:	IN CONFIDENCE	**Reference:**	H2025059306
To:	Hon Simeon Brown, Minister of Health		
Copy to:	Hon Casey Costello, Associate Minister of Health Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☐		

Contact for telephone discussion

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Minister's office to complete:

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☐ See Minister's Notes	☐ Withdrawn	

Comment:

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Extension of expiry date for specified biotechnical procedures- Xenotransplantation

Security level:	IN CONFIDENCE	**Date:**	28 February 2025
To:	Hon Simeon Brown, Minister of Health		

Purpose of report

1. This briefing seeks decisions on extending Part 7A of the Medicines Act 1981, that regulates xenotransplantation procedures, via an Order in Council. This part of the Medicines Act is set to automatically expire on 30 September 2025.

Summary

2. Xenotransplantation is the transplantation of tissue and organs between different species, and in particular the transplantation of animal tissue into humans. For example, the use of pig kidneys in kidney replacement surgery.

3. Part 7A of the Medicines Act, which regulates xenotransplantation, was originally inserted into the Medicines Act 1981 in 2002, to protect patient safety by ensuring xenotransplantation procedures, including (but not limited to) clinical trials, had appropriate oversight. Part 7A applies to medical procedures that involve the insertion or injection of 'living biological material' derived from an animal. Authorisation must be provided to carry out a xenotransplantation procedure using living biological material.

4. At the time the Part was added to the Act, it was envisaged that the Part would eventually be replaced with a proper regulatory regime. As such, the Part had an automatic expiry date, although this date could be extended via an Order in Council.

5. Part 7A is set to expire in September 2025. Without an extension, there would be no monitoring or regulatory oversight to protect patients from experimental medical procedures using living biological material, such as organ transplants involving living animal tissues. Until a comprehensive regime is established under the Medical Products Bill, this lack of regulation could expose patients to dangerous unregulated procedures and could expose the population to infections that cross the species barrier. The expiry date in Part 7A has been extended previously. The most recent extension assumed that this technology would be appropriately regulated under the Therapeutic Products Act 2023 (TPA). In December 2024, the TPA was repealed therefore a new decision is required on whether to extend Part 7A of the Medicines Act.

6. We recommend that the expiry date be extended to 30 September 2030 by an Order in Council, with the intention that xenotransplantation procedures will be regulated appropriately in the Medical Products Bill as a longer-term solution. This allows sufficient time for the Medical Products Bill to be implemented.

7. If you agree, Ministry Officials will draft a Cabinet Paper for June 2025 to seek agreement to defer the expiry date until 30 September 2030, or when the Medicines Act is repealed by the Medical Products Bill (whichever occurs earlier).

Recommendations

We recommend you:

a)	**Note** that Part 7A of the Medicines Act 1981 ensures procedures involving living biological material from animals are monitored and that safety, ethical and cultural considerations are taken into account	**Noted**
b)	**Note** that Part 7A will expire on 30 September 2025 unless extended	**Noted**
c)	**Note** that the extension of regulatory oversight of xenotransplantation procedures is needed to ensure patient safety and ethical concerns associated with this technology are appropriately managed	**Noted**
d)	**Note** that the expiry of Part 7A can be extended via Order in Council. A Cabinet paper can be provided in June 2025 for a Cabinet decision	**Noted**
e)	**Agree** to extend the expiry date of Part 7A of the Medicines Act, until 30 September 2030, by which time a new regulatory regime will be in place.	**Yes/No**

Maree Roberts
Deputy Director-General of Health
Strategy, Policy and Legislation
Date: 28/02/2025

Hon Simeon Brown
Minister of Health
Date:

Extension of expiry date for specified biotechnical procedures- Xenotransplantation

Background

What is xenotransplantation?

8. Xenotransplantation is the transplantation of tissue and organs between different species, and in particular the transplantation of animal tissue into humans. Examples of xenotransplantation for medical use include the transplantation of pig kidneys and heart valves, pig neuronal cells for the treatment of Parkinson's, and pig pancreatic cells for the treatment of diabetes.

9. Xenotransplantation stands at the intersection of innovative medical science and a complex regulatory landscape. It has long been signalled as a potential solution to the overwhelming shortage of human organs, tissues and cells available for transplantation. However, many proposed applications of xenotransplantation remain experimental.

10. Importantly, many routine procedures involving *processed* animal tissues (eg, heart valves and skin grafts) are not captured by the current restrictions. This is because those procedures involve tissues that have been through an extensive manufacturing process and they no longer contain 'living' cellular material. As such, extending Part 7A will not disrupt standard medical practice. However, more experimental procedures involving the transplant of living biological materials from animals (eg, whole organs) are currently in development. As there is no requirement for these procedures to be undertaken via a clinical trial in New Zealand, the restrictions in Part 7A play an important role in preventing inappropriate and unethical procedures.

Risks of xenotransplantation

11. There are safety risks associated with xenotransplantation, including the potential transmission of diseases, such as porcine-endogenous retrovirus, from animals to human patients when using living biological material. Xenotransplantation can also draw objections about its cultural and ethical appropriateness. As animal 'donors' cannot consent to the process, it is opposed by those who object generally to the use of animals in research or treatment.

12. The ethical and safety concerns surrounding xenotransplantation have led to the development of a multifaceted legislative framework globally, designed to ensure both the advancement of this field and the protection of public health.

13. Without Part 7A, New Zealand's existing regulatory regime for medical devices is inadequate to manage the real safety risks associated with xenotransplantation.

Current xenotransplantation regulatory activities approved under Part 7A

14. The Ethics team at the Ministry of Health has received one application for a xenotransplantation clinical trial in the last 8 years. From 2008-2015, Minsters of Health authorised a specified company, Living Cell Technologies Limited, to carry out a clinical

trial using xenotransplantation. This is the only company that has been given authorisation for a specified biotechnical procedure as listed in the Gazette.

15. We are only aware of two operating companies in New Zealand working on xenotransplantation research. Living Cell Technologies, mentioned above, has secured a critical service agreement with NZeno to breed and maintain pigs that will provide tissue for the third clinical trial of their treatment targeting Parkinson's disease.

16. However, the restrictions in Part 7A of the Medicines Act are not limited to clinical trials.

Expiry of Xenotransplantation provisions under Part 7A

17. Part 7A was added to the Medicines Act in 2002. Part 7A was originally set to expire in 2003, but the Government has extended the expiry multiple times via Orders in Council. In the long term, it has been the Government's intent that xenotransplantation be covered by new human tissue legislation and medical products legislation.

18. Without an extension, there would be no monitoring or regulatory oversight to protect patients from experimental medical procedures using living biological material from September 2025. Until a new regime is established, this lack of regulation could expose patients to dangerous unregulated procedures and could expose the population to infections that cross the species barrier. The only approval requirement would be from the Health and Disability Ethics Committee and then only if the procedure was undertaken as a clinical trial (ie, not as clinical practice).

19. As the Medical Products Bill is not expected to commence until late 2028, if Part 7A expires, real safety and ethical concerns associated with experimental xenotransplantation activities will not be appropriately addressed.

New Zealand's regulation of xenotransplantation is outdated, but Part 7A of the Medicines Act remains an important protection for patient safety

20. New Zealand's xenotransplantation regulations are prohibitive compared to comparable jurisdictions. However, this stringency is justified by the absence of comprehensive regulation of biological materials (animal and human) and medical devices under the Medicines Act 1981.

21. In the medium term, there is an opportunity in the Medical Products Bill to adopt more appropriate regulations for biological materials and xenotransplantation. The Bill would ensure products meet appropriate safety standards and protect the health and safety of patients, while not unnecessarily hindering innovation. As agreed by Cabinet in September 2024 [SOU-24-MIN-0115] a new Medical Products Bill will better align with the Government's priorities for timely access to safe, high-quality medical products which the Medicines Act does not adequately address.

22. However, it will take a number of years for the Medical Products Bill to be implemented and, without Part 7A of the Medicines Act in the interim, this technology will be unregulated, especially if experimental organ donation procedures move from the research phase to clinical practice.

We recommend that xenotransplantation should continue to be regulated given its unique safety risks and ethical and cultural considerations

23. Without Part 7A, New Zealand's existing regulatory regime for medical devices is inadequate to manage the real safety risks associated with xenotransplantation and the use of living biological material in clinical trials. As such, we recommend that you agree to develop an Order in Council to extend Part 7A of the Medicines Act until 2030, or until the Medical Products Bill commences.

Equity

24. There are substantial inequities in kidney disease prevalence, treatment access and long-term outcomes for different groups of New Zealanders. Māori and Pacific people are 4-5 times more likely to receive renal replacement therapy (dialysis or kidney transplant) for end-stage kidney disease than European New Zealanders, yet they have lower access to kidney transplants.

25. Xenotransplantation has long been signalled as a potential solution to the overwhelming shortage of human organs, tissues and cells available for transplantation. Risks associated with xenotransplantation can be more appropriately addressed in the Medical Products Bill. There is potential to address the greater need in Māori and Pacific populations.

Next steps

26. If you agree to develop an Order in Council to extend the expiry date of Part 7A of the Medicines Act, we will instruct the Parliamentary Counsel Office to draft the relevant Order. We would then prepare a paper for you to take to the Legislation Committee of Cabinet, seeking agreement for the Order to be presented to the Governor-General.

ENDS.