In Confidence

Office of the Minister of Health

Cabinet Social Outcomes Committee

Extending the current regulation of xenotransplantation procedures

Proposal

1 This paper seeks agreement to extend Part 7A of the Medicines Act 1981, which regulates xenotransplantation procedures, via an Order in Council. This part of the Medicines Act is currently set to automatically expire on 30 September 2025.

Relation to Government priorities

2 This paper aligns with the Government's priorities of prioritising patients and supporting innovation through the continuation of this legislation. It is consistent with Cabinet decisions to develop new legislation under the Medical Products Bill [SOU-24-MIN-0115].

Background

What is xenotransplantation?

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

4 Xenotransplantation is a potential solution to the serious shortage of human organs, tissues and cells available for transplantation. However, many proposed applications of xenotransplantation remain experimental.

5 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.

Part 7A of the Medicines Act

6 Part 7A of the Medicines Act 1981 applies to medical procedures that involve the insertion or injection of 'living biological material' derived from an animal. Xenotransplantation procedures using living biological material require authorisation by the Minister of Health, subject to application requirements as listed in the Gazette.

7 Xenotransplantation procedures involving tissue which no longer contain 'living' cellular material, due to extensive manufacturing processes, are not regulated under Part 7A.

8 There is no requirement for procedures involving xenotransplantation to be undertaken via a clinical trial in New Zealand, so the restrictions in Part 7A play an important role in preventing inappropriate, unsafe and unethical experimental procedures.

9 Part 7A was initially intended to provide for temporary measures, pending the development of a comprehensive legislative regime for xenotransplantation procedures. The expiry date in Part 7A has been extended multiple times previously. The most recent extension in 2020 assumed that this technology would be appropriately regulated under the Therapeutic Products Act 2023 and therefore set an expiry date of September 2025. In December 2024, the Therapeutic Products Act was repealed, therefore a decision is required on whether to again extend Part 7A of the Medicines Act.

Analysis

10 If Part 7A expires, the lack of regulation could expose patients to dangerous unregulated procedures and the population to infections that cross the species barrier.

11 Without Part 7A, approval would only be required from the Health and Disability Ethics Committee for procedures undertaken as a clinical trial (ie, not as clinical practice).

12 I 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 [SOU-24-MIN-0115], which is expected to commence in late 2028 at the earliest, to be implemented.

13 I recommend an Order in Council to extend Part 7A of the Medicines Act until 2030.

Cost-of-living Implications

14 The proposals in this paper are unlikely to have significant cost-of-living implications.

Financial Implications

15 The proposals in this paper have no financial implications.

Legislative Implications

16 Parliamentary Council Office will issue drafting instructions for an Order in Council if agreed by Cabinet.

Impact Analysis

Regulatory Impact Statement

17 The Ministry for Regulation has determined that this proposal is exempt from the requirement to provide a Regulatory Impact Statement on the grounds that it has only minor economic, social, or environmental impacts.

Climate Implications of Policy Assessment

18 The Climate Implications of Policy Assessment (CIPA) team has been consulted and confirms that the CIPA requirements do not apply to this proposal, as the threshold for significance is not met.

Population Implications

19 This decision maintains the status quo, so there are no particular population implications.

Human Rights

20 The proposals in this paper are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Use of External Resources

21 No external resources were used to produce this paper.

Consultation

22 The Ministry of Health consulted the following agencies on this paper: the Ministry of Business, Innovation and Employment, Health New Zealand, Environmental Protection Authority. The Department of Prime Minister and Cabinet and the Health Research Council were informed.

Communications

23 No communication activity is planned for this Cabinet Paper.

Proactive Release

24 This paper will be proactively released within 30 days of an Order in Council being enacted, with redactions as appropriate under the Official Information Act 1982.

Recommendations:

The Minister of Health recommends that the Committee:

1 **note** that Part 7A of the Medicines Act 1981 prohibits medical procedures that involve the insertion or injection of 'living biological material' derived from an animal, known as xenotransplantation, without the authorisation of the Minister of Health

2 **note** that Part 7A will expire on 30 September 2025 unless extended

3 **note** if Part 7A expires, there will be no monitoring or regulatory oversight to protect patients from experimental medical procedures using living biological material

4 **agree** to extend the expiry date of Part 7A of the Medicines Act, until 30 September 2030

5 **authorise** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to these recommendations via Order in Council

6 **note** that the Medical Products Bill is the Government's long-term solution to adopt more appropriate regulations for xenotransplantation.

Hon Simeon Brown

Minister of Health