

[IN CONFIDENCE]

Office of the Minister of Health
Chair, Cabinet

Deferral of the expiry of xenotransplantation provisions in the Medicines Act 1981 by Order in Council

Proposal

- 1 I propose that Cabinet agree to authorise the submission to the Executive Council of the Medicines (Deferral of Expiry of Part 7A) Order 2020. This is necessary to ensure continuing regulatory oversight of xenotransplantation procedures in New Zealand until a new regulatory regime under the Therapeutic Products Bill is in place.

Policy

Background

- 2 Xenotransplantation, a 'specified biotechnical procedure', is the transplantation of living biological material (including solid organs, tissues, or clusters of cells) from animals to humans. Xenotransplantation is a developing technology and clinical trials are underway internationally for its use in treatments for diseases including type-1 diabetes.
- 3 There are safety risks associated with xenotransplantation, including the potential transmission of disease from animals to humans. It can also draw objections about its appropriateness (in some cases for cultural or spiritual reasons). It is opposed by those who object generally to the use of animals in research or treatment.
- 4 Xenotransplantation is currently regulated by Part 7A of the Medicines Act 1981 (the Act). The Act prohibits xenotransplantation unless it is approved by the Minister of Health on a case-by-case basis, and only if the Minister is satisfied that robust safety and ethical criteria have been met:
 - 4.1 the conduct of the procedure or class of procedures does not pose an unacceptable risk to the health and safety of the public
 - 4.2 any risks posed by the conduct of the procedure or class of procedures will be appropriately managed
 - 4.3 any ethical, cultural and spiritual issues have been adequately addressed
- 5 Part 7A has been in place since 2002. Since then, only one company has received approval to undertake clinical trials in New Zealand, which involved the transplantation of porcine (pig) cells in the treatment of Parkinson's

disease and type-1 diabetes. These trials have ended and that company has no current plans for further clinical trials in New Zealand.

- 6 A further company has indicated that it intends to undertake clinical trials involving xenotransplantation of pig kidneys in New Zealand, but the company has not yet applied for regulatory approval.

Expiry of Part 7A of the Medicines Act 1981

- 7 Part 7A of the Act is subject to a sunset clause and will expire on 30 September 2020 unless deferred through an Order in Council. This expiry date was set in 2016 when Cabinet agreed that future regulation of xenotransplantation would be through the proposed Therapeutic Products Bill (the Bill) [refer SOC-15-MIN-0050 and SOC-16-MIN-0025], that will repeal and replace the Medicines Act.
- 8 The Bill will establish a modern regulatory scheme that will ensure the safety, quality and efficacy of all therapeutic products, including xenotransplantation procedures. The Ministry of Health is progressing work on the Bill and intends introducing it to the House in the next parliamentary term, if agreed by Cabinet.
- 9 If Part 7A expires, any future clinical trials using xenotransplantation would be unregulated until the new regime is in place. They would not require the approval of the Minister of Health and there would be no ongoing monitoring or regulatory oversight to ensure safety and other concerns are managed.

Policy Proposal

- 10 Given the risks and controversial nature of xenotransplantation procedures, I consider it appropriate that they be subject to ongoing regulatory oversight. I therefore propose that the expiry of Part 7A be deferred until 30 September 2025 through an Order in Council, by which time the new regulatory regime under the Therapeutic Products Bill should be in place.

Timing and the 28-day rule.

- 11 The Order in Council must be made before the current provisions in Part 7A expire on 30 September 2020. The Order has been drafted to come into force on 29 September 2020.
- 12 I propose that the 28-day rule be waived on the grounds that the Order will have little or no effect on the public. In addition, Part 7A has been in place since 2002 and its expiry has been deferred multiple times, with the result that there should be no expectation of it being allowed to expire before a new regulatory regime is in place.

Compliance

- 13 The Order in Council proposed in this paper will comply with each of the following:

- 13.1 the principles of the Treaty of Waitangi
- 13.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993
- 13.3 the principles and guidelines set out in the Privacy Act 1993
- 13.4 relevant international standards and obligations
- 13.5 the Legislation Guidelines (2018 edition), which are maintained by the Legislation Design and Advisory Committee.

Regulations Review Committee

- 14 There are no known grounds under which the Regulations Review Committee would draw the proposed Order in Council to the attention of the House of Representatives under Standing Order 319.

Certification by Parliamentary Counsel

- 15 The Order in Council has been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet, except that these regulations will come into force earlier than the 28th day after their notification in the Gazette.

Impact Analysis

- 16 The Regulatory Quality Team at the Treasury has determined that the regulatory proposals in this paper are exempt from the requirement to provide a Regulatory Impact Statement on the basis that they have no or minor impacts on businesses, individuals or not for profit entities.

Publicity

- 17 This is not a substantive policy or legislative change. No publicity is planned.

Proactive release

- 18 I intend to proactively release this paper, subject to any redactions.

Consultation

- 19 The following agencies were consulted on this paper and agree with the proposed approach: The Treasury; Ministries of Business Innovation and Employment, Environment, Primary Industries, and Justice; Te Puni Kōkiri, PHARMAC, the Environmental Protection Authority and the Parliamentary Counsel Office.
- 20 The Health and Disability Ethics Committees (HDECs) and the Department of the Prime Minister and Cabinet have also been informed.

Recommendations

I recommend that Cabinet:

- 1 **note** that Part 7A of the Medicines Act 1981 prohibits xenotransplantation procedures unless the Minister of Health is satisfied that robust safety and ethical criteria have been met
- 2 **note** that Part 7A of the Medicines Act 1981 will expire on 30 September 2020 unless extended by an Order in Council
- 3 **note** that if Part 7A of the Medicines Act 1981 expires there will be no regulatory approval or oversight of xenotransplantation procedures in New Zealand
- 4 **note** that Cabinet has previously agreed that xenotransplantation procedures will be regulated under the new regulatory regime that will be introduced through the proposed Therapeutic Products Bill [refer SOC-15-MIN-0050 and SOC-16-MIN-0025]
- 5 **note** that the Ministry of Health is continuing to advance work on the Therapeutic Products Bill and intends introducing the Bill to the House in the next parliamentary term, if agreed by Cabinet
- 6 **agree** that the expiry of Part 7A of the Medicines Act 1981 be deferred until 30 September 2025, through an Order in Council commencing 29 September 2020, by which time the new regulatory regime is expected to be in place following the enactment of the Therapeutic Products Bill and supporting regulations
- 7 **authorise** the submission to the Executive Council of the Medicines (Deferral of Expiry of Part 7A) Order 2020
- 8 **note** that a waiver of the 28-day rule is sought:
- 8.1 so that the Order in Council can come into force before the expiry of Part 7A of the Medicines Act 1981 on 30 September 2020; and
- 8.2 on the grounds that the Order will have little or no impact on the public
- 9 **agree** to waive the 28-day rule so that the Order in Council can come into force on 29 September 2020.

Authorised for lodgement

Hon Chris Hipkins

Minister of Health



Cabinet

Minute of Decision

This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.

Medicines (Deferral of Expiry of Part 7A) Order 2020

Portfolio **Health**

On 7 September 2020, Cabinet:

- 1 **noted** that Part 7A of the Medicines Act 1981 prohibits xenotransplantation procedures unless the Minister of Health is satisfied that robust safety and ethical criteria have been met;
- 2 **noted** that Part 7A of the Medicines Act 1981 will expire on 30 September 2020 unless extended by an Order in Council;
- 3 **noted** that if Part 7A of the Medicines Act expires there will be no regulatory approval or oversight of xenotransplantation procedures in New Zealand;
- 4 **noted** that in 2015 and 2016, Cabinet agreed that xenotransplantation procedures will be regulated under the regulatory regime that will be introduced through the Therapeutic Products Bill [SOC-15-MIN-0050, SOC-16-MIN-0025];
- 5 **noted** that:
 - 5.1 the Ministry of Health is continuing to advance work on the Therapeutic Products Bill;
 - 5.2 Cabinet's agreement will be sought to introduce the Bill to the House in the next parliamentary term;
- 6 **agreed** that the expiry of Part 7A of the Medicines Act be deferred until 30 September 2025, through an Order in Council commencing on 29 September 2020, by which time the new regulatory regime is expected to be in place following the enactment of the Therapeutic Products Bill and supporting regulations;
- 7 **authorised** the submission to the Executive Council of the Medicines (Deferral of Expiry of Part 7A) Order 2020 [PCO 23169/2.0];
- 8 **noted** that a waiver of the 28-day rule is sought:
 - 8.1 so that the Order can come into force before the expiry of Part 7A of the Medicines Act on 30 September 2020;
 - 8.2 on the grounds that the Order will have little or no impact on the public;

- 9 **agreed** to a waiver of the 28-day rule so that the Order can come into force on 29 September 2020.

Michael Webster
Secretary of the Cabinet

Proactively released