

In Confidence

Office of the Minister of Health
Chair, Cabinet Legislation Committee

Medicines (Deferral of Expiry of Part 7A) Order 2025

Proposal

- 1 This paper seeks authorisation for submission to the Executive Council of the Medicines (Deferral of Expiry of Part 7A) Order 2025 (the Order).

Policy

- 2 On 19 May 2025, Cabinet agreed to extend the expiry of Part 7A of the Medicines Act (xenotransplantation) until 30 September 2030 [CAB-25-MIN-0159].
- 3 Xenotransplantation is the transplantation of organs or tissues from animals into humans. Part 7A is a temporary measure until a comprehensive framework is established by the Medical Products Bill.

Timing and 28-day rule

- 4 I intend to submit the Order to Cabinet for their consideration on 28 July 2025. The Order will take effect on 29 September 2025. No waiver of the 28-day rule is sought.

Compliance

- 5 The Order in Council complies with each of the following:
 - 5.1 the principles of the Treaty of Waitangi;
 - 5.2 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;
 - 5.3 the principles and guidelines set out in the Privacy Act 2020;
 - 5.4 relevant international standards and obligations;
 - 5.5 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.

Regulations Review Committee

- 6 There are no grounds for the Regulations Review Committee to draw the Order in Council to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

- 7 The Order in Council has been certified by the Parliamentary Counsel Office (PCO) as being in order for submission to Cabinet.

Impact Analysis

- 8 The Ministry for Regulation has exempted this proposal from requiring a Regulatory Impact Statement, as it has only minor economic, social, or environmental impacts.

Publicity

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

Proactive release

- 10 This paper will be proactively released upon enactment of the Order in Council, with redactions as appropriate under the Official Information Act 1982.

Consultation

- 11 The following agencies were consulted: the Ministry of Business, Innovation and Employment, Health New Zealand, and the Environmental Protection Authority. The Department of the Prime Minister and Cabinet and the Health Research Council were informed. PCO was consulted on the drafting of the Order.

Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 note that on 19 May 2025 Cabinet agreed to extend expiry of Part 7A of the Medicines Act to 30 September 2030 [CAB-25-MIN-0159];
- 2 note that the Medicines (Deferral of Expiry of Part 7A) Order 2025 will give effect to the decision [CAB-25-MIN-0159] referred to in recommendation 1;
- 3 authorise the submission to the Executive Council of the Medicines (Deferral of Expiry of Part 7A) Order 2025;
- 4 note that the Medicines (Deferral of Expiry of Part 7A) Order 2025 will come into force on 29 September 2025;
- 5 note that the Medical Products Bill, currently under development, is the Government's long-term solution to regulating xenotransplantation.

Authorised for lodgement

Hon Simeon Brown
Minister of Health