



Cabinet Social Outcomes Committee

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.

Modernising Regulation of Medicines and Medical Devices: High-Level Regulator Settings

Portfolio Associate Health (Hon Casey Costello)

On 23 October 2024, the Cabinet Social Outcomes Committee (SOU):

Background

- 1 **noted** that in May 2024, SOU invited the Associate Minister of Health (Hon Casey Costello) (the Associate Minister), in consultation with the Associate Minister of Health (Hon David Seymour), to report back on proposals for future direction for regulation of medicines and medical devices, and for natural health products [SOU-24-MIN-0032];
- 2 **noted** that in September 2024, SOU agreed to core policy elements of a Medical Products Bill (the Bill) to replace the Medicines Act 1981 and for the Associate Minister to issue initial drafting instructions for a modern, risk-proportionate law to regulate medicines and medical devices (medical products) [SOU-24-MIN-0115];

Form and functions of the Regulator

- 3 **noted** that the core functions of the regulator will relate to product approvals, licences for controlled higher-risk activities, post-market surveillance, and compliance activities, as agreed by SOU in September 2024 [SOU-24-MIN-0115];
- 4 **noted** that the Associate Minister has considered four options for the form of the medical products regulator:
 - 4.1 a branded business unit within the Ministry of Health;
 - 4.2 an independent statutory officer supported by a branded business unit within the Ministry of Health;
 - 4.3 a new Departmental Agency with an independent statutory officer;
 - 4.4 a new Crown Entity;
- 5 **agreed in-principle** to the form of the medical products regulator being an independent statutory officer supported by a branded business unit within the Ministry of Health, subject to a report back on costings to the Cabinet Expenditure and Regulatory Review Committee (EXP) in December 2024;

High-level settings for the funding of the regulator

- 6 **noted** that the Associate Minister has considered three options for funding the medical products regulatory regime:
- 6.1 the status quo of the regulator charging fees to mostly cost recover its operations, with Crown funding providing the balance of operating costs;
 - 6.2 full cost-recovery from industry, with no Crown funding;
 - 6.3 extending the status quo mixed funding model (first option) to include levies for different sectors and actors within the medical products supply chain;
- 7 **agreed in-principle** to the medical products regulatory regime being funded by extending the status quo under the Medicines Act 1981 to include levies for different sectors and actors within the medical products supply chain, subject to a report back on costings to EXP in December 2024;

Implementation of the Medical Products Bill

- 8 **noted** that to implement the Medical Products Bill the following is required:
- 8.1 development of highly technical secondary legislation;
 - 8.2 development of and transition to a medical products regulator;
 - 8.3 development of a digital platform to enable the new regime;

9 s 9(2)(f)(iv)

Next steps

- 10 **invited** the Associate Minister, in consultation with the Associate Minister of Health (Hon David Seymour) to report back to EXP in December 2024 on the preferred way forward, including costings;
- 11 **agreed** that the December 2024 Cabinet paper only consider the first two options for the entity form of the regulator referred to in paragraph 4, reflecting the higher costs and risks of establishing a new entity compared to a branded business unit within the Ministry of Health.

Jenny Vickers
Committee Secretary

Attendance: (see over)

Present:

Rt Hon Christopher Luxon
Rt Hon Winston Peters
Hon David Seymour
Hon Nicola Willis (Chair)
Hon Erica Stanford
Hon Paul Goldsmith
Hon Louise Upston
Hon Mark Mitchell
Hon Tama Potaka
Hon Matt Doocey
Hon Melissa Lee
Hon Nicole McKee
Hon Casey Costello
Hon Penny Simmonds
Hon Nicola Grigg
Hon Karen Chhour

Officials present from:

Office of the Prime Minister
Officials Committee for SOU
Ministry of Health

PROACTIVELY RELEASED

PROACTIVELY RELEASED