



# Cabinet Social Outcomes Committee

## Minute of Decision

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### Medical Products Bill: Reducing Regulation and Other Policy Matters

**Portfolio** Associate Health (Hon Casey Costello)

On 13 August 2025, the Cabinet Social Outcomes Committee (SOU):

#### Background

1 **noted** that in September 2024, SOU:

- 1.1 agreed to replace the Medicines Act 1981 (the Medicines Act) with modern regulation of medicines and medical devices under a Medical Products Bill (the Bill); and
- 1.2 invited the Associate Minister of Health (Hon Casey Costello) (the Associate Minister) to report back with further policy proposals on topics including regulating pharmacies, advertising, supporting exporters, statutory timeframes, and offences and penalties;

[SOU-24-MIN-0115]

#### Pharmacy ownership

- 2 **agreed** that the Medicines Act restrictions on the ownership of community pharmacies should not be carried over into the Bill;
- 3 **agreed** to create a supervisory pharmacist role with formal responsibility for pharmacy standards and compliance in any company which includes more than one pharmacy;

#### Advertising

- 4 **agreed** that the Bill will include a clear and consistent definition of advertising, drawing on the definition in the Australian Therapeutic Goods Act 1989, and applying to all medical products;
- 5 **agreed** that the Bill not treat the following as advertising:
  - 5.1 public safety announcements, recall orders, public health campaign statements approved by the Director-General of Health, the pharmaceutical schedule, any statement required by law, and any communication exempted via regulations;
  - 5.2 reporting of news or a matter of public concern, research, study or education, criticism or review, fundraising for a specific product for a specific person or people, and advocating for a change to government policy; and

- 5.3 clinical trial recruitment material approved by a recognised ethics committee;
- 6 **agreed** to continue to permit direct-to-consumer advertising of prescription medicines;
- 7 **agreed** to a regulation-making power to enable controls on specific advertising practices;
- 8 **agreed** to continue to prohibit promotion of unapproved medical products and off-label use of medicines, except for:
- 8.1 products which do not need an approval;
- 8.2 promotion authorised by the Director-General of Health;
- 8.3 promotion at trade shows and medical conferences;

### Statutory timeframes

- 9 **agreed** that the Bill will carry over all specific statutory timeframes from the Medicines Act, including any added via the current Medicines Amendment Bill, and enable the ability to set other decision timelines in secondary legislation;
- 10 **agreed** that decision-makers will be required under the Bill to report annually on performance against statutory timeframes;
- 11 **agreed** to enable a partial refund of fees if a decision has not been made within statutory timeframes;
- 12 **agreed** that the Bill will include timeframes for applicants, and power to lapse applications if information is not provided in time;

### Supporting exporters

- 13 **agreed** that the Bill will provide for medical product exporters to be issued with certification needed by importing countries, and that this will be cost-recovered;
- 14 **agreed** that the Bill will require medical products exporters to register, and that exporters will be subject only to general legal duties such as record-keeping;

### Offences and penalties

- 15 **agreed** that, where the Crown is carrying out activities in the same way as a private actor (e.g., manufacturing a device) it will have the same legal liability;
- 16 **agreed** that the Bill will include a civil pecuniary regime;
- 17 **agreed** to an offence of improper inducement of a health practitioner to make a clinical decision about a medical product;
- 18 **agreed** to a fit and proper person test to be applied as part of decision-making on a licence, permit, or other approval;

### Enabling Medsafe to continue to carry out regulatory functions under the Medical Products Bill

- 19 **agreed** that regulatory functions being formally vested in a statutory officer supported by the Ministry of Health (in practice through Medsafe);

- 20 **agreed** that the statutory officer must be a public servant (or be employed as a public servant on appointment), appointed by the Director-General of Health;
- 21 **agreed** that Medsafe and the regulation of medical products will continue to be funded mostly through cost-recovery, with the addition of levies;
- 22 **agreed** that the objective of the statutory officer will be to operate the medical products regulatory regime independently, while being:
- 22.1 accountable to the Director-General of Health for the general performance of their functions and powers;
- 22.2 subject to general policy directions issued by the Minister of Health in relation to medical products;
- 22.3 required to publish a regulatory strategy setting out their performance expectations and how they will perform their functions;
- 23 **agreed** to draw on the list of regulator functions in section 339 of the Therapeutic Products Act 2023 as well as subparts 2 (cost recovery), 3 (information), 4 (decision making and exercise of powers), and 6 (review of Regulator's decisions) of Part 9 of the Therapeutic Products Act, with modifications consistent with Cabinet's decisions;

#### Drafting instructions and timing

- 24 **authorised** the Associate Minister to issue drafting instructions to give effect to the decisions under SOU-25-MIN-0101;
- 25 **noted** that the Medical Products Bill holds a category 6 priority on the 2025 Legislation Programme (drafting instructions to be issued by the end of 2025);
- 26 **noted** that the Associate Minister intends to seek agreement from the Cabinet Legislation Committee to introduce the Bill to Parliament in 2026.

Jenny Vickers  
Committee Secretary

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#### Present:

Hon David Seymour  
Rt Hon Winston Peters  
Hon Chris Bishop (Chair)  
Hon Erica Stanford  
Hon Paul Goldsmith  
Hon Dr Shane Reti  
Hon Mark Mitchell  
Hon Tama Potaka  
Hon Matt Doocey  
Hon Nicole McKee  
Hon Casey Costello  
Hon Penny Simmonds  
Hon Karen Chhour  
Hon Nicola Grigg  
Hon Scott Simpson

#### Officials present from:

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