



Cabinet Social Policy Committee

SOC-15-MIN-0049

Version 1.0

Minute of Decision

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Therapeutic Products Regulation Paper 1: Context and Overview

Portfolio **Health**

On 18 November 2015, the Cabinet Social Policy Committee:

- 1 **noted** that in November 2014 the Minister of Health (the Minister) announced the cessation of work on a joint regulator with Australia (ANZTPA) and the commencement of work on a comprehensive domestic regulatory regime for therapeutic products covering medicines, medical devices and cell and tissue therapies [CAB Min (14) 36/22];
- 2 **noted** that:
 - 2.1 a Therapeutic Products Bill (the Bill) to repeal and replace the Medicines Act 1981 holds a category 6 priority on the government's Legislation Programme (drafting instructions to be issued this year) [CAB Min (15) 5/7];
 - 2.2 the paper under the submission SOC-15-SUB-0049, and the associated paper under the submission SOC-15-SUB-0050 *Therapeutic Products Regulation: Paper 2 Proposals for a Therapeutic Products Bill* will enable drafting instructions to be developed for the key elements of the Bill;
- 3 **noted** that the Minister will report to the Social Policy Committee in March 2016 on a range of other matters, including prescribing, dispensing and administration of therapeutic products, clinical trial arrangements and the proposed form of the regulator, with a view to further drafting instructions being issued;
- 4 **noted** that the Minister intends to introduce the Bill to the House in late 2016 for passage during 2017;
- 5 **agreed** that, prior to the introduction of the Bill, the Minister will release an exposure draft of the Bill for consultation along with a statement of the policy to be contained in subordinate legislative instruments;
- 6 **noted** that in August 2015, the Cabinet Economic Growth and Infrastructure Committee agreed to repeal, via the Statutes Repeal Bill, provisions of the Medicines Act 1981 that were introduced through the Medicines Amendment Act 2013 that have a default commencement date of 1 July 2017 as these are no longer necessary or desirable in light of the development of the new regulatory regime [EGI-15-MIN-0027];

- 7 **agreed** that the objectives for the therapeutic products regulatory regime are that it:
- 7.1 meets expectations of risk management and assurance of acceptable safety;
 - 7.2 results in efficient and cost effective regulation;
 - 7.3 is flexible, durable, up-to-date, and easy to use;
 - 7.4 ensures high-quality, robust and accountable decision-making;
 - 7.5 is able to sustain capable regulatory capacity;
 - 7.6 supports New Zealand's trade and economic objectives;
 - 7.7 is trusted and respected;
 - 7.8 supports consumer access and individual responsibility for care
- 8 **agreed** that the above objectives will be best met by:
- 8.1 an enabling legislative framework where primary legislation sets the purpose of the regime, principles that set boundaries for the scope and development of subordinate legislative instruments, enforcement powers and accountability arrangements;
 - 8.2 regulatory requirements that reflect international norms, standards and frameworks;
 - 8.3 a regulator that can exercise regulatory powers and associated administrative powers effectively, is accountable, and able to engage internationally;
- 9 **noted** that the regulatory approval processes will involve a mix of unilateral recognition, use of other regulators work, and assessment by the regulator.

Suzanne Howard
Committee Secretary

Present:

Hon Bill English
Hon Paula Bennett (Chair)
Hon Dr Jonathan Coleman
Hon Hekia Parata
Hon Anne Tolley
Hon Dr Nick Smith
Hon Michael Woodhouse
Hon Peseta Sam Lotu-Iiga
Hon Maggie Barry
Hon Craig Foss
Hon Jo Goodhew
Hon Louise Upston
Hon Te Ururoa Flavell
David Seymour MP

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Chief Executive, Department of the Prime Minister and Cabinet
Chief Executive, Department of the Prime Minister and Cabinet
Minister for the Environment
Minister of Commerce and Consumer Affairs

Officials present from:

Office of the Prime Minister
Officials Committee for SOC