CBC-21-MIN-0117

Cabinet Business Committee

Minute of Decision

Therapeutic Products and Natural Health Products Regulatory Scheme

Portfolio **Health**

On 6 October 2021, the Cabinet Business Committee:

Background

1 **noted** that the paper under CBC-21-SUB-0117 is part of work to modernise New Zealand's therapeutic products and natural health products regulatory scheme, central to which is repealing the Medicines Act 1981 and replacing it with the Therapeutic Products Bill;

2 s 9(2)(f)(iv) [redacted];

Establishing a new regulator and funding settings

3 **noted** that in December 2018, the Cabinet Social Wellbeing Committee invited the Minister of Health and the Minister of State Services to report back on the recommended institutional form of the therapeutic products regulator and cost-recovery policy for the regulatory scheme [SWC-18-MIN-0176];

4 **noted** that either a branded business unit or departmental agency, each with an independent statutory officer, would meet the government's objectives for a regulator that is independent, transparent, accountable, able to sustain regulatory capability and capacity, responsive, and flexible;

5 **noted** that the branded business unit with an independent statutory officer is less likely to result in fragmentation in the sector, and more likely to make a stronger contribution to system coherence and realising the government's vision of pae ora/healthy futures for all New Zealanders;

6 **agreed** that the therapeutic products and natural health products regulator be established as a branded business unit of the Ministry of Health, with an independent statutory officer;

7 **agreed** that the Director-General of Health must appoint a person as the independent statutory officer, as an employee of the Ministry of Health, after being satisfied that the person has the appropriate experience and expertise to perform the functions and duties and exercise the powers of the role;

8 **noted** that, regardless of entity form, the regulator may require discretion to meet the market for remunerating specialist roles, and that this is justified by the cost-recovery arrangements;

9 **noted** the importance of ensuring that the regulator's funding is protected and cannot be used for other functions of the Ministry (except to meet the regulator's share of overheads);

10 **noted** that the principles guiding the development of the cost-recovery model will include effectiveness, efficiency, transparency, consultation, equity, and simplicity;

11 **agreed** that the new regulatory scheme be funded through Crown funding and cost recovery consistent with Table 1 in paragraph 68 of the paper under CBC-21-SUB-0117 as follows:

11.1 fees will be charged for approval, accreditation, and certification activities, export certification, and audits of individual businesses;

11.2 levies will be charged for developing and maintaining market access, and monitoring and testing compliance;

11.3 Crown funding will be applied to policy advice, legislative development, international engagement and cooperation, guidance, development of export standards, investigations and enforcement action including prosecutions, and drug abuse containment;

12 **agreed** that the cost-recovery model include provision for exemptions and waivers from fees and levies, and that these may be granted on an individual or class basis;

13 **invited** the Minister of Health to issue drafting instructions to amend the draft Therapeutic Products Bill to give effect to the Committee's decision over the entity form, and including the regulator's functions and objectives in the Bill;

14 **invited** the Minister of Health to report back to the Cabinet Social Wellbeing Committee in the second half of 2022 on the recommended cost-recovery model as part of the package of regulations relating to the new scheme s 9(2)(f)(iv) [redacted]

15 **noted** that in addition to costs associated with the transition to a new regulatory regime, the regulator will require a higher level of operational funding to match its increased regulatory role;

16 s 9(2)(f)(iv) [redacted]

[redacted]

[redacted]

[redacted]

17 s 9(2)(f)(iv) [redacted]

18 s 9(2)(f)(iv) [redacted]

Offences and penalties

19 **noted** that in March 2016, Cabinet agreed that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings, and infringement notices [SOC-16-MIN-0025];

20 **agreed** that a civil pecuniary penalty regime be included in the Bill;

21 **noted** that the Ministry of Health will continue to work with the Ministry of Justice to identify those existing offences within the Therapeutic Products Bill where the conduct engaged in is in breach of the law and should be deterred, but does not warrant the denunciatory and stigmatising effects of a criminal conviction;

22 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above decisions;

Direct-to-consumer advertising of prescription medicines

23 **noted** that the paper under CBC-21-SUB-0117 fulfils the requirement to report to Cabinet on whether or not increased regulation of direct-to-consumer advertising of named prescription medicines is warranted [SWC-19-MIN-0088];

24 **noted** that direct-to-consumer advertising of prescription medicines is effectively regulated in New Zealand now through existing provisions of the Medicines Act, general consumer protection legislation, self-regulation by the advertising industry and the therapeutic product industry, and both government regulation and professional standards for healthcare professionals;

25 **agreed** to retain the approach taken in the draft Therapeutic Products Bill, which is to continue the current policy settings for regulating direct-to-consumer advertising of prescription medicines, and provide the new therapeutic products regulator with updated regulatory tools.

Jenny Vickers
Committee Secretary

Present:
Rt Hon Jacinda Ardern (Chair)
Hon Grant Robertson
Hon Kelvin Davis
Hon Dr Megan Woods
Hon Chris Hipkins
Hon Carmel Sepuloni
Hon Andrew Little
Hon David Parker
Hon Nanaia Mahuta
Hon Poto Williams
Hon Kris Faafoi
Hon Dr David Clark

Officials present from:
Office of the Prime Minister
Department of the Prime Minister and Cabinet