



# Cabinet Social Wellbeing Committee

## Minute of Decision

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### Therapeutic Products Regulatory Scheme: Overview and Consultation on Bill Exposure Draft

Portfolio                      Health

On 5 December 2018, the Cabinet Social Wellbeing Committee:

#### Background

- 1        **noted** that the Medicines Act 1981 is no longer fit-for purpose and a new regulatory scheme for therapeutic products is required;
- 2        **noted** that in 2015 and 2016, the previous government took decisions on matters to be covered in a new Therapeutic Products Bill (the Bill) that would repeal and replace the Medicines Act 1981 with a modern, comprehensive regulatory regime for therapeutic products in New Zealand [SOC-15-MIN-0049, SOC-15-MIN-0050, SOC-16-MIN-0025];
- 3        **noted** that in 2016, the previous government agreed that, because of the technical and complex nature of the Bill, the Minister of Health would release an exposure draft of that Bill and supporting consultation material [SOC-16-MIN-0025];

#### Next Steps

- 4        **noted** that the Minister of Health has reviewed the policy decisions taken by the previous administration and, with some exceptions, recommends that the draft Bill giving effect to the decisions in SOC-15-MIN-0049, SOC-15-MIN-0050 and SOC-16-MIN-0025 proceed to public consultation as an exposure draft;
- 5        **noted** that there is a high level of stakeholder interest in the Bill and an expectation of public consultation;
- 6        **agreed** that the Minister of Health release an exposure draft of the Bill by the end of 2018 for public consultation;
- 7        **noted** that the exposure draft will be supported by a consultation document and questions and answers to assist discussion;
- 8        **noted** that coalition and support partners will have an opportunity to review the exposure draft of the Bill and consultation document before they are released;

**Policy changes/new policy**

- 9 **noted** that, as the Minister of Health has reviewed the work to date, and as drafting has proceeded, a small number of issues have emerged where a different approach is now recommended;
- 10 **agreed** that the Bill include provision for an unknown type of therapeutic product (currently called ‘Type-4’) to be regulated should such a thing emerge in future;
- 11 **agreed** that the Bill provide for individuals to carry into the country a reasonable quantity of a lawfully prescribed prescription medicine for personal use, but that the ability for individuals to receive prescription medicines from overseas through the post be curtailed;
- 12 **agreed** that the Bill enable health practitioners to supply pharmacy-only (or category 3) medicines in certain circumstances;
- 13 **agreed** that, in order to inform further advice to Cabinet, the consultation document seek views on the following two options for pharmacy licensing in the new regulatory scheme:
- 13.1 strengthened accountability through pharmacist ownership and effective control (Minister of Health’s initial preference);
- 13.2 open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy;
- 14 **agreed** that the Bill provide for review of specified regulatory decisions by:
- 14.1 requiring the regulator to convene a review panel that comprises at least three people with suitable skills, who were not involved in the original decision, and at least one of whom is a lawyer with at least 7 years’ experience;
- 14.2 requiring that the panel review the merits of the original decision on the basis of the information available when the decision was made;
- 14.3 enabling the panel to confirm the original decision or set the decision aside and refer the matter back to the regulator to be reconsidered and a fresh decision made;
- 14.4 enabling appeal to the District Court in respect of review panel and regulator decisions;
- 15 **agreed** that the Bill not contain a requirement on the regulator to establish committee(s) for specific matters and that this issue be revisited, if necessary, as part of the work on institutional form;

**Natural health products**

- 16 **noted** the non-reinstatement of the Natural Products Bill would have the unintended consequence of bringing natural health products within the ambit of the Therapeutic Products Bill if appropriate steps to mitigate this are not undertaken;
- 17 **agreed**, in order to not unduly further delay the Therapeutic Products Bill and to allow due process in respect of the ongoing work on the regulation of natural health products, that natural health products be excluded from the Therapeutic Products Bill as far as is possible;

- 18 **agreed** that the consultation document to be released with the exposure draft of the Bill make clear that the government is to consider options for the regulation of natural health products and that it will therefore exclude them from the Therapeutic Products Bill as far as is possible;
- 19 **noted** that the natural health product exclusion will be drafted and included in the Bill that is introduced to the House of Representatives;
- 20 **noted** that this issue will attract considerable attention during the consultation process and during the Select Committee stages of the Bill;

### Reports-back

- 21 **invited** the Minister of Health and Minister of State Services to report back to the Cabinet Social Wellbeing Committee (SWC) in March 2019 on the recommended institutional form of the therapeutic products regulator and cost recovery policy for the regulatory scheme;
- 22 **invited** the Minister of Health and the Minister for Food Safety to report back to SWC in May 2019 on the options for the regulation of natural health products;
- 23 **invited** the Minister of Health to report back to SWC within four months following the close of consultation on the following matters:
- 23.1 the overall outcomes of consultation on the exposure draft of the Bill and consultation document;
- 23.2 whether increased regulation of direct-to-consumer advertising of named prescription medicines is warranted;
- 23.3 a recommended approach to pharmacy licensing criteria.

Jenny Vickers  
Committee Secretary

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#### Present:

Rt Hon Jacinda Ardern  
Rt Hon Winston Peters  
Hon Grant Robertson  
Hon Phil Twyford  
Hon Chris Hipkins  
Hon Andrew Little  
Hon Carmel Sepuloni (Chair)  
Hon Dr David Clark  
Hon Stuart Nash  
Hon Jenny Salesa  
Hon Tracey Martin  
Hon Willie Jackson  
Hon Julie Anne Genter  
Jan Logie, MP

#### Officials present from:

Office of the Prime Minister  
Department of the Prime Minister and Cabinet  
Office of the Chair of SWC  
Officials Committee for SWC

#### Hard-copy distribution:

Minister of Health