



Cabinet Social Policy Committee

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Minute of Decision

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Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill

Portfolio **Health**

On 18 November 2015, the Cabinet Social Policy Committee:

- 1 **agreed** that drafting instructions be provided to the Parliamentary Counsel Office for a Therapeutic Products Bill (the Bill) that includes the following settings;

Purpose and principles

- 1.1 a statement encompassing the concept that the purpose of the Bill is to ensure acceptable safety, quality and efficacy or performance of therapeutic products across their lifecycle to protect public health and welfare;
- 1.2 that the concept in 1.1 above includes the regulation of manufacture, supply, import, export and promotion of therapeutic products; on the setting of standards in relation to therapeutic products; the post-market monitoring of therapeutic products, and the enforcement of requirements;
- 1.3 a set of principles that give effect to the purpose and set the parameters for the regulatory regime and that express the intention that:
 - 1.3.1 the expected benefits of therapeutic products should outweigh the known risks of causing harm in the treatment population;
 - 1.3.2 regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use;
 - 1.3.3 regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests;
 - 1.3.4 an identified person is responsible for managing the risks associated with each therapeutic product on the market, and will generally be the person who is responsible for marketing that product;
 - 1.3.5 regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public;
 - 1.3.6 regulator should co-operate with international peer regulators and take relevant international standards and practice into account;

- 1.3.7 compliance costs should be appropriate to the benefit:risk profile;
- 1.3.8 regulation should support innovation and competition;

Definitions

- 1.4 definitions of the terms therapeutic product, therapeutic purpose, responsible person, approval holder, and licensee;
- 1.5 high-level definition of categories of therapeutic products;
- 1.6 the ability for the regulator to declare something to be, or not to be, a therapeutic product and the category of product;

Approvals

- 1.7 a requirement that therapeutic products are approved, unless an approval is not required, and the ability for the regulator to issue an approval;
- 1.8 a requirement that material changes to approved therapeutic products also be approved;
- 1.9 the ability for the regulator to place conditions on an approval;
- 1.10 the ability for the regulator to modify, suspend or revoke an approval;
- 1.11 the ability for approvals to be issued for a defined duration;
- 1.12 definitions of generic classifications that apply to therapeutic products based on those that apply to medicines currently (prescription, restricted, pharmacy-only, general sales);
- 1.13 the ability for the regulator to classify products as a condition of approval;
- 1.14 enable recognition of other jurisdictions assessments/approvals and third party evaluators;

Data protection

- 1.15 provisions for the protection of information supporting an application for regulatory approval of a new medicine from the date the approval is granted, consistent with New Zealand's obligations under the Trade-Related Aspects of Intellectual Property Rights agreement and as set out in the Medicines Act 1981;

Activities licensing

- 1.16 a requirement that, unless done under licence issued by the regulator, controlled activities are prohibited in respect of therapeutic products, including:
 - 1.16.1 manufacturing, including packing and labelling;
 - 1.16.2 supply, including wholesale, hawking, and retail of therapeutic products (licence holders must also undertake these activities consistent with product classification);
 - 1.16.3 operating a pharmacy;

- 1.17 the ability for the regulator to issue licenses for up to a three year period and set and vary conditions on a licence within that time;

Promotion/advertising

- 1.18 a requirement that advertisements and promotions in respect of therapeutic products be truthful, not misleading and socially responsible;

Compliance, enforcement and penalties

- 1.19 inspection powers, including the ability to require information;
- 1.20 search and seizure powers based on those in the Medicines Act 1981 and the Search and Surveillance Act and including a warranted search power for dwelling houses and marae where an offence against the Act is reasonably suspected;

Vigilance

- 1.21 obligations on the regulator to monitor the safety of therapeutic products and to provide information to approval holders (noting that obligations for vigilance are also imposed on approval holders through the approvals process);

Administration arrangements

- 1.22 that regulatory powers and associated administrative powers are held independent of the Minister of Health;
- 1.23 an ability for the Minister of Health to direct the regulator on matters of government policy and not in respect of a particular product or person;
- 1.24 the following accountability arrangements:
- 1.24.1 that, except where already provided for by the Legislation Act, instruments made by the regulator be disallowable instruments and subject to review by the Regulations Review Committee;
 - 1.24.2 that, in making legislative instruments, the regulator consult appropriately;
 - 1.24.3 that the regulator establish mechanisms for industry and consumer engagement;
 - 1.24.4 that the regulator be transparent about its processes;
 - 1.24.5 financial and non-financial reporting;
- 1.25 the ability for the regulator to establish technical advisory committees as it requires;
- 1.26 a requirement that the regulator establish a committee or committees to provide advice, as needed, on therapeutic product assessment, classification, and safety monitoring;
- 1.27 a requirement that the regulator ensure committees have members with suitable skills, including (but not limited to) consideration of the need for members with knowledge of medicine, pharmacy and consumer perspectives;

- 1.28 the ability for committee processes to be determined by the regulator as a matter of policy;

Review and appeal

- 1.29 the establishment of an independent review committee administered by the Ministry of Health to hear appeals against regulatory decisions;

Cost recovery

- 1.30 a requirement that the regulator recover its costs through fees and levies where these costs are not met through Crown funding;
- 1.31 a requirement that fees and levies are reviewed within three years of first being set;

Transitional provisions

- 1.32 provisions which enable products regulated under the Medicines Act 1981 to transition to the new regulatory regime;
- 1.33 provisions which enable regulatory requirements to apply in a staged manner to medical devices and cell and tissue therapies;
- 1.34 provisions that require a review of the Therapeutic Products Act within five years of the end of the transition period;

Regulations

- 1.35 the ability for regulations to be made in respect of:
- 1.35.1 Review Committee matters including who can apply for review and the ability to charge for review;
 - 1.35.2 classification;
 - 1.35.3 fees and levies;
 - 1.35.4 accountability arrangements;
 - 1.35.5 exempted products (including pharmacy compounding);
 - 1.35.6 licensing;

Regulator-made instruments

- 1.36 the ability for instruments to be made by the regulator in respect of:
- 1.36.1 how an application for an approval should be made;
 - 1.36.2 closer definition of categories of product;
 - 1.36.3 standards and requirements that will apply to products and associated activities (including for example, manufacture, product recall, vigilance);
 - 1.36.4 the application of classifications;

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- 1.36.5 exempted products;
- 1.36.6 requirements to be met in respect of obtaining licenses;
- 1.36.7 requirements to be met in respect of meeting advertising requirements;

2 **noted** that:

- 2.1 the Ministry of Health will discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments further with the Parliamentary Counsel Office and the Legislation Design Advisory Committee;
- 2.2 the Minister of Health will report back on the outcome of the above discussions in March 2016 if any changes are proposed;

3 **noted** that the obligations in the TransPacific Partnership on data protection for pharmaceuticals (including biological pharmaceuticals) can be met within New Zealand's current policy settings and practice;

4 **noted** that:

- 4.1 the Minister of Health's initial view is that current restrictions on pharmacy ownership as a condition for licensing are not necessary to achieve the safety objectives of the regulatory scheme (including restrictions on medical practitioners having an interest in pharmacies);
- 4.2 the Minister of Health will report to Cabinet and seek agreement on the most appropriate licensing arrangements for the Bill following sector consultation on the Draft Pharmacy Action Plan;

5 **noted** that the costs of developing the regime are currently met from the Ministry of Health's baseline funding (including some funding from the Ministry's third party revenue baseline funding) and that the costs of implementation will be managed within usual budget processes or factored into fee setting for the new regulatory regime;

6 **noted** that the Minister of Health will report to the Social Policy Committee during March 2016 on further policy issues with a view to further drafting instructions being authorised; these include prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework and the form of the regulator.

Suzanne Howard
Committee Secretary

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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-liga
Hon Maggie Barry
Hon Craig Foss
Hon Jo Goodhew
Hon Louise Upston
Hon Te Ururoa Flavell
David Seymour MP

Officials present from:

Office of the Prime Minister
Officials Committee for SOC

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