SOC-16-MIN-0025

Cabinet Social Policy Committee

Minute of Decision

Therapeutic Products Regulation: Further Policy Approvals

Portfolio **Health**

On 30 March 2016, the Cabinet Social Policy Committee (SOC):

Previous consideration

1 **noted** that in November 2015, SOC:

1.1 agreed the objectives for a new therapeutic products regulatory regime, the means to achieve those objectives, and that drafting instructions be provided for the key elements of a Therapeutic Products Bill (the Bill) to repeal and replace the Medicines Act 1981;

1.2 noted that the Minister of Health (the Minister) would report to the SOC during March 2016 on policy issues to inform further drafting instructions, including prescribing, dispensing and administering therapeutic products, clinical trial arrangements, the detail of the offences and penalties framework, the form of the regulator, and pharmacy licensing arrangements;

1.3 noted that the Ministry of Health would discuss the appropriate placement of regulatory requirements in the hierarchy of legislative instruments with the Parliamentary Counsel Office and the Legislation Design Advisory Committee, and that the Minister would report back if any changes were proposed;

[SOC-15-MIN-0049, SOC-15-MIN-0050]

Clinical trials

2 **noted** that clinical trials are conducted within a robust safety and ethical framework that can offer a number of social and economic benefits to New Zealand;

3 **agreed** that the therapeutic products regulatory regime cover trials of all therapeutic products (all medicines, medical devices, cell and tissue therapies, and hybrid products) with requirements commensurate with the risk each trial presents;

4 **agreed** that the regulator have the necessary powers to enable it to set requirements, approve trials, change conditions, access information, inspect, audit and take action to ensure safety (including revoking approval);

5 **agreed** that the regulator be required to establish a committee to provide advice, as needed, on applications for clinical trials;

6 **agreed** that the current timeframe for considering clinical trial applications remain at 45 working days and that this be contained in a subordinate instrument;

7 **noted** that the Minister has instructed officials to streamline and improve coordination and cooperation between the regulatory and ethical approval processes for clinical trials;

Cell and tissue therapeutic product regulation

8 **confirmed** that all cell and tissue therapeutic products be within the scope of the therapeutic products regulatory regime (including minimally-manipulated tissue for immediate transplantation and xenotransplantation) with requirements calibrated to the risk of the products and the way they are used in clinical practice;

9 **agreed** that the regime include a mechanism to enable minimally-manipulated tissue (both for immediate transplantation and banked for later transplantation) to not be subject to the requirement for pre-market approval;

10 **agreed** that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to the requirement for activities licences;

11 **agreed** that the regime include a mechanism to enable minimally-manipulated tissue for immediate transplantation to not be subject to import and export requirements;

12 **agreed** that the decisions in paragraphs 9 - 11 above be drafted so as to allow the settings to be changed in the future should issues arise that warrant it;

13 **noted** that both legislative placement and the accountability arrangements agreed to by SOC for the regulatory regime will ensure that there is appropriate government oversight of, and sector engagement about, any proposal to put additional regulatory requirements in place for minimally-manipulated tissue for immediate transplantation;

Prescribing and dispensing

14 **agreed** that controls on prescribing authority (including conditions on that practice) should sit under the Health Practitioners Competence Assurance Act 2003;

15 **agreed** that the Health Practitioners Competence Assurance Act 2003 be amended to include mechanisms for prescribing authority to be part of a health practitioner's Scope of Practice (including amendments to prescribing authority);

16 **agreed** that the above mechanisms include the Minister deciding whether to approve the parameters of prescribing proposed for inclusion in a Scope of Practice;

17 **noted** that current prescribing authorities will be carried over into the new regime;

Pharmacy licensing

18 **noted** that:

18.1 pharmacy licensing is aimed at ensuring the integrity of the supply chain of therapeutic products;

18.2 Cabinet has agreed to continue the international norm of licensing pharmacies [SOC-16-MIN-0050];

19 **agreed** that the therapeutic products regulatory regime provide for the regulator to:

19.1 issue licences, for up to three years;

19.2 require information;

19.3 assess whether applicants for licences are fit-and-proper persons (or of good repute to hold a licence);

19.4 require licence applicants to identify a Responsible Pharmacist for the day-today oversight of the licenced pharmacy;

19.5 require licence applicants to also identify a Supervisory Pharmacist with responsibility for overseeing the implementation of professional pharmacy standards and licence conditions;

19.6 set conditions on licences as appropriate to maintain pharmacy standards and manage and monitor risks;

20 **agreed** that requiring pharmacist ownership of pharmacies is unnecessary to achieve the objectives of the regime and that the provisions in paragraph 19 above provide sufficient mechanisms to ensure that professional pharmacy practice standards are upheld;

21 **agreed** that licences for supply not necessarily be restricted to fixed physical premises, and that additional conditions may be set to manage risks associated with new supply models;

22 **agreed** that the therapeutic products regulatory regime prohibit prescribers from benefitting from their prescribing activities through an investment in pharmacies, but not prevent sensible integrated service initiatives from developing;

23 **noted** that the separation between pharmacy licensing and contracting will continue and that a pharmacy licence does not entitle the holder to a services contract;

Import and export

24 **agreed** that importing therapeutic products be a licensed activity;

25 **agreed** that an exception to the requirement to hold an import licence should be provided for personal use, so long as other regulatory requirements are met;

26 **agreed** that the export of therapeutic products require notification accompanied by evidence that the product meets the regulatory standards of the importing country;

27 **noted** that the regulator will continue to issue export certificates for therapeutic products for New Zealand exporters on request to facilitate export to other jurisdictions;

28 **noted** that parallel importing of all therapeutic products will be prohibited as a result of requiring approvals for all therapeutic products;

29 **agreed** that the exemption permitting the Crown to parallel import medicines be replaced with a credible alternative that will enable the Crown to source alternative supplies of therapeutic products in appropriate circumstances;

Offences and penalties framework

30 **agreed** that the Bill include a hierarchy of enforcement tools that include tiered criminal offences, enforceable undertakings, and infringement notices;

Regulator form

31 **agreed** that the regulator not be established as a Crown Entity;

32 **agreed** that the powers of the regulatory regime (and associated administrative powers) be vested in the chief executive as defined in the State Sector Act 1988;

Interface with the Hazardous Substances and New Organisms Act 1996

33 **agreed** that the new therapeutics regulator and the Environmental Protection Authority will work together to ensure the application process for therapeutic products containing new organisms is efficient and effective;

34 **agreed** that the Bill provide the ability to prescribe disposal requirements and prohibit the importation and distribution of medicines that contain an environmentally hazardous substance on the recommendation of the Environmental Protection Authority, on its own initiative or at the request of the regulator;

Drafting instructions

35 **noted** that the Bill has a category five priority on the 2016 Legislation Programme (to be referred to a select Committee in 2016);

36 **invited** the Minister to issue drafting instructions to the Parliamentary Counsel Office to give effect to paragraphs 2 – 34 above;

37 **authorised** the Minister to make further policy decisions for the purposes of preparing the exposure draft of the Bill where the matter is consistent with the decisions made by Cabinet on the Bill;

38 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office in respect of straight-forward matters that are in the Medicines Act that should be carried through to the new regulatory regime (with appropriate adjustments to reflect decisions made by Cabinet on the new regulatory regime);

Placement of provisions

39 **directed** officials to continue to work with the Parliamentary Counsel Office and the Legislation Design Advisory Committee on placement matters with a view to the legislation being as enabling as possible, while also providing certainty as to the scope of the regulatory regime and its requirements;

Report backs

40 **invited** the Minister to report to SOC on institutional arrangements for the regulator, including whether the regulator should be the Department or a Departmental Agency, no later than October 2016;

41 **invited** the Minister report to SOC by June 2016 on extending Part 7A of the Medicines Act that controls specified biotechnical procedures (including xenotransplantation);

Process matters

42 **agreed** that the Minister:

42.1 approve the release of the Bill exposure draft and supporting consultation material later in 2016;

42.2 report on the outcomes of consultation when approval is sought to introduce the Bill (unless there are significant matters to be addressed by Cabinet earlier);

43 **noted** that, to facilitate stakeholder engagement, the Ministry of Health intends to release before May 2016, with any necessary redactions made as consistent with the Official Information Act 1982:

43.1 the paper under SOC-16-SUB-0025;

43.2 the papers under SOC-15-SUB-0049 and SOC-15-SUB-0050;

43.3 the regulatory impact statements associated with the above papers.

Jenny Vickers
Committee Secretary

Present:
Hon Bill English
Hon Paula Bennett (Chair)
Hon Dr Jonathan Coleman
Hon Anne Tolley
Hon Judith Collins
Hon Jo Goodhew
Hon Nicky Wagner
Hon Te Ururoa Flavell

Officials present from:
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Department of the Prime Minister and Cabinet
The Treasury
Office of the Chair of SOC
Office of the Minister of Health
Ministry of Health
Office of the Minister of Corrections
Officials Committee for SOC

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