Therapeutic Products Bill-consultation

Research

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Therapeutic Products Bill: Research Session

1. Purpose & design of the Bill
2. Scope & Definitions
3. Product & activity controls
4. Clinical trials
5. Transition

Purpose & Design of the Bill

Purpose:

The purpose of this Act is to protect personal and community health by-

(a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and

(b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products.

Design

- Principles-based framework with three subordinate tiers.

Guiding principles of the Bill

The Regulator and any other person exercising a power under this Act must be guided by the purpose of this Act and the following principles:

(a) the likely benefits of therapeutic products should outweigh the likely risks associated with them:

(b) regulation of therapeutic products should-

(i) be proportionate to the risks posed by the products; and

(ii) support the timely availability of therapeutic products:

(c) the administration of this Act should be carried on in an open and transparent manner:

(d) there should be co-operation with overseas regulators, compliance with international obligations, and, if appropriate, alignment with international standards and practice.

There will be less detail in legislation and more in the regulations and regulator-made instruments

Instrument	Content	Process
Therapeutic Products Act	Primary legislation sets out: • the purpose of the Act • provides a set of principles and criteria to set the parameters of the regulatory regime • sets boundaries for the scope and development of subordinate legislative instruments • contains the primary elements of the regulatory regime • provides enforcement powers • sets out accountability arrangements	Legislative instrument, made by Parliament
Regulations	Regulations will contain further detail on: • matters not appropriately dealt with in regulator-made instruments (such as fee setting) • matters to do with accountability • key elements of the regulatory regime that will remain relatively stable and which are significant to the design of the regulatory requirements **Schedule 3 lists the matters that can be specified in regulations**	Legislative instrument, made by the Governor-General by Order and Council Regulations will be subject to review by the Regulations Review Committee
Rules	Contain the detail of the regulatory requirements **Schedule 3 lists the matters that can be specified in rules**	Legislative instrument, made by the regulator. Subject to review by the Regulations Review Committee.
Notices	Contain administrative detail of the scheme **Schedule 3 lists the matters that can be specified in notices**	Non-legislative instrument, made by the regulator. The regulator must not issue a notice unless satisfied that doing so if necessary or desirable to promote the purposes of the Act; and it is no broader than is reasonable necessary to address matter that gave rise to it

What is a therapeutic product?

A product is a **therapeutic product** if-

(a) it is intended for **use in, on, or in relation to humans** for a therapeutic purpose; or

(b) it is **specified in the regulations** to be a TP; or

(c) it is intended for use as an **active ingredient of a medicine**.

A naturally occurring thing …. may become a TP if it is changed from its naturally occurring state…..

BUT…a product that would otherwise be a therapeutic product under (a) is not a therapeutic product if it is a **natural health product**.

[Section 16 (paraphrased)].

What is a therapeutic purpose?

The following are **therapeutic purposes**:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury

(b) influencing, inhibiting, or modifying a human physiological process

(c) testing the susceptibility of humans to a disease or an ailment

(d) influencing, controlling, or preventing human conception

(e) testing for human pregnancy

(f) investigating, replacing, modifying, or supporting part of a human's anatomy

(g) supporting or sustaining human life

(h) disinfecting medical devices

(i) a purpose connected with a purpose referred to in paragraphs (a) to (h).

The Bill would regulate 4 types of product

- Medicines
- Active ingredients of medicines (AMIs)
- Medical devices
- Type-4 products.

What is a medicine?

The distinguishing feature of a medicine is that it:

achieves, or is likely to achieve, its principal intended action-

(A) by pharmacological, immunological, or metabolic means; or

(B) by means of the action of something that comprises, contains, or is derived from human or animal cells or tissues.

Regulator's notices can also be used to declare something to be a medicine, AMI, medical device or type-4 product.

What is a medical device?

The distinguishing feature of a medical device is that it:

achieves, or is likely to achieve, its principal intended action **by means other than**-

(A) pharmacological, immunological, or metabolic means; or

(B) the action of something that comprises, contains, or is derived from human or animal cells or tissues

(although its function may be assisted by the means in A and B).

Regulator's notices can also be used to declare something to be a medicine, AMI, medical device or type-4 product.

Clinical trial for a medicine means an investigation:

(a) that involves administering the product to, or using it on, 1 or more individuals (**subjects**); and

(b) that is undertaken to obtain information about its quality, safety, or efficacy or performance by doing 1 or more of the following

(A) discovering or verifying its clinical, pharmacological, or other pharmacodynamic effects

(B) identifying any adverse reactions to it

(C) studying its absorption, distribution, metabolism, or excretion; and

(c) to which 1 or more of the following apply

(i) the assignment of each subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice:

(ii) the decision to administer or use the product is taken together with the decision to include the subject in the study

(iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the subjects.

Clinical trial for a medical device means an investigation that:

(a) involves administering the product to, or using it on, 1 or more individuals (subjects); and

(b) is undertaken to obtain information about its quality, safety, or efficacy or performance; and

(c) to which 1 or more of the following applies:

(i) the assignment of each subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice:

(ii) the decision to administer or use the product is taken together with the decision to include the subject in the study:

(iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the subjects.

The scheme would consist of two broad components

1. **Product approval requirements**
    - Generally, with some exceptions, a TP can't be imported or supplied unless it is approved.
    - There will be different approval pathways possible
2. **Controlled activity restrictions**
    - The Bill regulates who is allowed to carry out certain activities involving therapeutic products (called controlled activities) and how those activities are carried out

In addition, the Bill also:

- Enables obligations to be imposed on people who in the course of business: import, supply, administer, use, or have possession of, any TPs
- Imposes restrictions on advertising
- Prohibits things such as tampering with, or misrepresenting, a TP.

Conducting a clinical trial requires an authorisation

A licence would be the usual way of authorising this controlled activity

- It would spell out the scope of what is permitted & also authorise the supply of the unapproved trial product for use in that trial

The licence holder must be a fit and proper person to be a licensee; **and**

- a person normally resident in NZ; or
- a body corporate that is incorporated in NZ; or
- the Crown

The responsible person(s) named on the licence must:

- be a person normally resident in NZ; or a body corporate that is incorporated in NZ; **and**
- be a fit and proper person & agree to undertake the role
- meet qualifications, training & competency, requirements in the Rules.

The criteria for granting a CT licence require the regulator to be satisfied that:

- The licensee & responsible person(s) meet the criteria
- The resources (includes human & financial, premises, equipment, procedures) are adequate & suitable
- Relevant persons have knowledge & will be able to comply
- An **ethics approval is in force** for the trial (or an "ethics approval entity" certifies it is not required for that trial)
- Any other criteria specified in Rules.

A timely and risk-based approach to CT licensing

- There would be a risk-appropriate approach for licensing and for trial requirements that was reflective of international norms. This would mean that “first use in humans” studies would receive more scrutiny than trials using only approved products
- We would expect the regulatory & ethics approval processes to run in parallel and be facilitated by on-line application tools
- We would expect the regulator to set performance times for processing applications that at least matched those achieved currently and to report its performance results publicly.

A licence:

- Would normally be issued for 3 years
- Could be subject to conditions
- Could be varied
- Could be suspended or cancelled

The regulator would be able to audit the CT activities

There would be a publicly accessible **register of licences.**

Getting ready for the new scheme

Before the scheme can commence all of the following events must have occurred:

- The Bill must have received Royal Assent
- Regulations must be developed (following consultation), signed by the Governor-General, published and in force
- Rules and Notices must be developed (following consultation), published and in force.

The new Act, regulations, rules and notices would all come into force on the same date (the commencement date for the scheme).

There is likely to be a gap of around two years between Royal Assent and commencement. During this time, planning and preparations for transition can begin.

The transition period begins on commencement date - so perhaps around late 2022 or early 2023.

What happens on and after commencement?

The Bill gives temporary transition authorisations for clinical trials that are lawfully underway before commencement:

- **Trials approved under section 30 of the Medicines Act are automatically given a temporary licence** that allows the trial to continue on the same basis. However:
    - Within 12 months after commencement, the person who made the application under the Medicines Act must apply for a new scheme licence. **As soon as they have done that, their temporary approval continues on until the regulator determines their application.** Note that no fee may be charged for creating this new licence.

For pending clinical trial applications under s 30 of the Medicines Act

The Bill allows the Regulator to treat the application as if it were an application to conduct a clinical trial under the new scheme.

Existing trials without a Medicines Act approval

Existing trials that did not require an approval under the Medicines Act are automatically given a temporary licence that allows the trial to continue on the same basis. However:

- Within **6 months** after commencement, the principal investigator for the trial must apply for a licence under the new scheme to carry on the trial activity.
- **As soon as they have done that, their temporary approval continues on until the regulator determines their application.**

What next

- Sector forums in March
- Submissions due by 18 April
- Analysis of submissions & report back to Cabinet
- Draft Bill amended, as required
- Draft Bill introduced to Parliament
- Select Committee process (which usually includes a public submission process)
- Development of regulations, rules and notices – will involve consultation on detail of the scheme.