New Zealand
Speech-language
Therapists' Association
Te Kāhui Kaiwhakatikatika
Reo Kōrero o Aotearoa

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Therapeutic Products Bill

Submission 5th March 2023

We are writing this submission on behalf of the *New Zealand Speech-Language Therapists' Association (NZSTA), which represents the speech-language therapy community in Aotearoa New Zealand.

Our key messages

1. Use of the term *Health Practitioner*

In section 14 Interpretation – the Bill states:

Health practitioner means a person who—

(a) is a health practitioner as defined in section 5 of the Health Practitioner Competence Assurance Act 2003; and

(b) holds a current practising certificate under that Act

While the HPCA covers many allied health professions, several health professionals, such as speech-language therapists and audiologists, self-regulate and do not come under the HPCA Act and, therefore, risk being excluded unintentionally from the bill.

In the NZSTA's experience, policymakers and drafters do not always understand this distinction well.

Speech-language therapists and audiologists use many medical devices – from tongue depressors to various diagnostic tools and software such as endoscopes and x-ray imaging.

Thus wherever this definition of a health practitioner is used and intended to apply, then the wording in the bill needs to ensure that all health professionals who may currently or in the future produce, supply, import, export or in some way use these medicines/devices that they are not prevented from doing so.

There are some controlled activities, including clinical trials using medical devices - is this a problem for SLTs (other self-regulated professions) as they will most likely conduct trials involving medical devices?

We would recommend the following amendment to cover SLTs, audiologists and all other self-regulating allied health professions:

Health practitioner means a person who—

(c) is a health practitioner as defined in section 5 of the Health Practitioner Competence Assurance Act 2003; or equivalent self-regulating professional body; and

(d) holds a current practising certificate under that Act or with their professional body.

2. Controlled Activities

Speech-language therapists (SLTs) regularly use medical devices in clinical practice and clinical trials. These include:

- conducting an endoscopic evaluation of swallowing (FEES) with a medical device called an endoscope.
- completing a videofluoroscopic swallow study (VFSS) using a medical imaging x-ray machine.
- conducting surface EMG which assesses muscle function by recording muscle activity from the surface above the muscle on the skin.
- using expiratory muscle strength trainers to strengthen muscles to improve breathing, cough, swallowing, and speech.

Speech-language therapists undergo rigorous training to be competent in these procedures.

The bill (section 69) appears to suggest that speech-language therapists will be prohibited from participating in the controlled activity of a clinical trial when using a medical device unless they have a special license, permit or subpart 3.

Currently, speech-language therapists who wish to conduct a clinical trial will seek ethics approval.

The prohibition and need to obtain a license/permit adds to another layer of bureaucracy and complexity.

3. Market authorisation

The NZSTA supports the purpose of the Bill, which is to regulate products to ensure the safety, quality, efficacy and performance of products over their life cycle.

There is no approval system for medical devices under the Medicines Act 1981. There is no mandatory requirement for medical devices to be approved by any medical device regulator before being supplied in New Zealand. Notification to the WAND database does not mean or imply that Medsafe has assessed a medical device in terms of quality, safety, efficacy, or performance. It is, though, a mandatory requirement for importers, exporters and New Zealand manufacturers to advise the Director-General of Health, via the WAND database, of the devices supplied here.[1]

Therefore, the NZSTA supports Part 4 of the Bill, which sets out the market authorisation requirements before a product can be imported and/or supplied. In particular, the NZSTA supports clause 119:

[1] https://medsafe.govt.nz/regulatory/DevicesNew/3-2Explanation.asp - accessed 13 February 2023

The Regulator must evaluate the product to determine—

(1) (a) whether the following are satisfactorily established:

(i) if it is a medicine, its safety, quality, and efficacy for its intended authorised indications; or

(ii) if it is a medical device, its safety, quality, and performance for its intended authorised indications; and

(1)(b) whether the likely benefits of the product outweigh the likely risks associated with it.

(2) The nature and extent of the Regulator's evaluation of the product must be appropriate and proportionate having regard to—

(a) the likely benefits of, and risks associated with, the product; and

(b) the extent of any previous evaluation of the product or a related product; and

(c) any matters set out in the regulations; and

(d) all of the circumstances of the case.

The NZSTA supports clause 140 in particular, which requires the sponsor of a product to ensure that the product meets the product standards. It agrees that standards may be specified in rules relating to the manufacturer's quality management system, packaging and labelling and product or consumer information.

4. Market surveillance and adverse event reporting

Previous drafts of this Bill featured mandatory adverse event reports by product sponsors. The NZSTA is disappointed to see this has been removed from this draft of the Bill. The market surveillance clauses do not appear sufficient to warrant the removal of mandatory adverse event provisions.

The NZSTA would like to see these provisions reinstated.

5. Regulations and Rules

The NZSTA requests a period of consultation on any regulations and rules which are subsequently developed.

In addition, the NZSTA requests consultation obligations imposed on the Regulator for any decision-making affecting an industry (for example., when considering the level of risk for a particular

medical device that impacts an industry group).

***Who is the New Zealand Speech-Language Therapists' Association**

The New Zealand Speech-language Therapists' Association (NZSTA), established in 1946, represents speech-language therapists (SLTs). NZSTA supports over 1,100 registered speech-language therapists nationally. Well over 90 per cent of the workforce are registered members.

The Association operates a self-regulatory process that provides for –

- annual practising certificates
- a clear scope of practice
- code of ethics
- complaints process
- programme accreditation of tertiary speech and language courses, and the approval of international speech-language therapy qualifications to ensure equivalency with New Zealand standards.
- a structured supervisory framework for new graduates or return-to-practice therapists
- continued quality assurance of its registered professionals.

Speech-language therapists study, diagnose and treat communication disorders, including difficulties with speaking, listening, understanding language, reading, writing, social skills, stuttering and using voice.

They work with people of all ages who have difficulty communicating because of developmental delays, stroke, brain injuries, learning disability, intellectual disability, cerebral palsy, dementia and hearing loss, and other problems that affect speech and language.

A speech-language therapist can also help people who experience difficulties swallowing food and drinking safely.

Speech-language therapists work in various settings, including schools, hospitals, courts, prisons, childcare centres, or a client's home.

Speech-language therapists complete a four-year bachelor's degree or a master's in speech-language therapy.

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