

Welcome to our August 2023 newsletter. This exciting newsletter is full of the latest developments that will keep you up-to-date with our industry.

It is best to view this in your browser.

THERAPEUTIC PRODUCTS BILL



On 26 July 2023 the Therapeutic Products Bill received Royal assent, becoming the <u>Therapeutic Products Act (2023)</u>.

Most provisions in the Act will not come into effect until mid-2026. Until then, the Ministry of Health (Manatū Hauora) will be busy developing the necessary rules and regulations to support the new therapeutic products regulatory regime. The Ministry will also be establishing the Regulator to administer the Act.

The new regime will be flexible enough to support innovation, while ensuring effective control over quickly evolving health technologies. It will also align with international standards and uphold the quality of regulation currently carried out by the Ministry.

As well as replacing and modernising the regulatory arrangements for medicines, the Act provides fit-for-purpose regulation of medical devices, and cell, gene and tissue therapies, which are currently not fully regulated.

Implementing the Act is a large-scale and complex programme of work.

It includes three major workstreams:

- Secondary legislation creating policy, rules, regulations, and regulatory instruments to support the new therapeutic regulatory regime
  - o Secondary legislation will be consulted on.
- 2. **IT platform** building a stable and scalable IT platform to support regulatory functions.

3. **The Regulator** – appointing an independent statutory officer as the Regulator and establishing a branded business unit within the Ministry of Health.

The scale, scope and complexity of work remaining to be undertaken before 2026 is significant and will require extensive consultation and engagement with the sector.

ATSNZ will continue to work in collaboration with health sector industry bodies while the regulations are developed and consulted on.

ATSNZ DISABILITY EXPO - 1 & 2 November 2023



Just over two months out and our event management team is working to fill the additional space, which we opened up as a result of the main hall being fully booked and enquiries to exhibit continue to be made.

We decided to incorporate a "have a

go" area outside of the main hall, so there is more space to try out exhibitors products. Depending on how many additional booths get filled, this space will either be located close to where Able Axcess have their booth, or it will be in the side wing of the main hall. This space will be managed so that it can be used safely.

The floorplan can be viewed by clicking the box on this webpage: https://www.atsnzexpo.nz/book-your-space

Whaikaha and Accessable have submitted their abstracts to be included in the seminar programme. We are still waiting for the ACC and Enable abstract, but have good faith they will come through. This 'funders' session will lead into the networking session we have planned at the close of day 1.

The seminar programming team have selected the presentations from those that were submitted by the due date of 31 July. There will be a good quality programme, with a good varitey of topics of interest to health professionals and end users. The finalized programme will become available to us all early in September.

**ENABLE UPDATE** 



become a major frustration for a good many of our members.

They are currently in the process of developing a survey that will collect your feedback on the situation.

We've been asked to review the survey they are developing and we'll

do so, when they have fully prepared the draft. Expect the survey to go out in September and when it does, it would be very worthwhile to participate.

WHAIKAHA UPDATE



Since our last newsletter we have had two further meetings with Whaikaha (EMS Portfolio manager), Enable, Accessable and a delegation of OTs, taking us to four meetings now, with

the next one planned early in September. We expect that there still will be a few more, before we have an agreed outcome that suits all participants.

Katie Noble and Jason Clare continue to provide information and insights on behalf of all our members that experience the burden of the current trials process. Together we have confidence that this working group will come to a solution that will benefit all parties.

On 1 August 2023 the Office for Disability Issues (ODI) was integrated into Whaikaha - Ministry of Disabled People.

The ODI team will continue their work as part of the Policy, Strategy and Partnerships Group within Whaikaha, including partnering on the New Zealand Disability Strategy and Action Plan, interagency advice based on the UNCRPD, and advice for the Minister for Disability Issues.

Whaikaha have stood up their internal structure as of 1 August. You can read more about this via the following link.

https://www.whaikaha.govt.nz/n...

ATSNZ AGM - 31 August 2023

Our AGM is but two days away and we have sent out all material for the meeting and requests to confirm



attendance, either in person or online.

We have quorum for a meeting so decisions can be made.

We look forward to a presentation from Sophia Malthus after the close of the AGM and this will be enjoyed

together with a light working lunch. Needless to say, we look forward to seeing you there.

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