Assistive Technology Suppliers New Zealand

MARCH 2023

Assistive Technology Suppliers New Zealand (ATSNZ) opposes the Bill in its current form.

ATSNZ supports the purpose of the Therapeutic Products Bill, as set out in the Bill's explanatory note, to protect, promote, and improve the health of all New Zealanders by providing for the acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients, and the safety and quality of natural health products across their life cycle.

ATSNZ supports the requirement for medical devices entering the New Zealand market to demonstrate that they meet an internationally recognised standard for safety and performance.

As manufacturers, importers, and distributors of medical devices, we recognise therapeutic products carry both benefits and risks, and agree with the Bill's guiding principle for regulating therapeutic products: that a product's likely benefits should outweigh its likely risks and that regulation should be proportionate to those benefits and risks.

However, the Bill in its current form, particularly in the way it proposes to treat medical devices, will undermine both that guiding principle and the other principles listed in the Bill, to wit that the regulation of therapeutic products should support:

- timely access to products,
- open and well-functioning markets,
- innovation,
- choice of, and equity of access to, therapeutic products.

Adopting the recommendations contained in this submission would create a regulatory regime that meets the Bill's objectives and is aligned with its principles.

<u>Approving and registering medical devices</u>

- ***ATSNZ recommends a system that provides for risk-stratified autonomous approval and registration of devices submitted with documentation recognised by competent authorities. The register database should be searchable by the public and the industry, and auditable by the regulator (algorithmically and manually), and the process should incorporate appropriate penalties for non-compliance.***
- ***ATSNZ recommends post market surveillance should remain the primary tool to ensure that medical devices continue to be safe and to perform well in the real world, and to ensure action is taken if the risk of continuing to use a medical device outweighs the benefits.***
- ***ATSNZ recommends market authorisation should not be required for the export of medical devices, because it should be sufficient that they meet all the requirements imposed by a regulator in the receiving market.***

Manufacturers and suppliers of medical devices in New Zealand have long operated under a "light-touch" regulatory regime.

Currently, there is no requirement for medical devices to be approved by any medical device regulator prior to being supplied in New Zealand. However, under section 38 of the Medicines Act 1981, the Director-General of Health may require the sponsor of a medical device to satisfy her of

the safety of that medical device, if she has reason to believe that the device is unsafe. **There is no evidence that a regulatory regime of this type is more likely to result in any harm to patients when compared to more onerous regulatory regimes**.

The Bill proposes that therapeutic products, including medical devices, must receive one of three types of market authorisation before they can be imported into, exported from, or supplied in New Zealand.

These market authorisations would be based on an evaluation by a newly established Regulator of a product's safety, quality, performance.

Under the current regime, a device's sponsor, (the individual who imports, exports, or manufactures the device – either themselves or through an agent) is required to advise the Director-General of Health, via Medsafe's WAND (web-assisted notification of devices) database, of medical devices that are exported from, imported in, or manufactured in this country.

This database was established by the Medicines (Database of Medical Devices) Regulations 2003.

This regime provides straightforward access to the New Zealand market for importers and distributors, thereby promoting choice of, and equity of access to, medical devices for all New Zealanders. Public health authorities require proof of WAND notification and proof of compliance to standards as certified by overseas competent authorities (e.g. FDA, TGA, CE Marking) in tender applications for device supply, thereby assuring the safety and efficacy of devices.

ATSNZ recognises the government's wish to introduce greater rigour to the process by which medical devices come to market in New Zealand. However, our view is that this could be better achieved by enhancements to the current system, rather than by the regime proposed in the Bill.

For example, sponsors could be required to notify WAND before commencing any sales or pre-sales promotional activity, thereby allowing the Regulator to carry out a risk-based evaluation of the device before it becomes available; the database could be made searchable (by both market participants and the public), as is the case with its Australian equivalent; and penalties for non-notification could be increased to further incentivise the desired behaviour.

The Bill does not only seek to impose a disproportionate level of regulation onto the supply of medical devices within New Zealand: it also introduces a requirement for the Regulator to approve the export of any medical device. This would make New Zealand unique among the countries with which we trade and threaten a developing export industry worth some $760 million per year that various governments have previously championed and encouraged.

By including a requirement for manufacturers of medical devices to obtain export market authorisation, the Bill creates the potential for negative outcomes in overseas markets, and risks causing economic damage, as well as negative health outcomes for patients in countries outside the regulators' jurisdiction.

The definition of an export authorisation implies the criteria for approval would be less rigorous than those required to gain a New Zealand authorisation. Given exporters of medical devices are required to satisfy the conditions imposed by the Regulators in their destination markets, it would make sense that the export authorisations should not apply where a medical device is being exported to a market that has stringent quality management systems and other checks (e.g. the US, Australia, etc), it is difficult to see who would benefit, were this part of the Bill to become law.

As it stands, the Bill will mean there will be two sets of requirements for exporters to meet, rather than just the one from the export market. Again, it is hard to see who would benefit from this.

Harmonisation

- ***ATSNZ recommends the Bill be reviewed and as required, adjusted to incorporate internationally recognised definitions and procedures from competent authorities, such as the TGA and FDA, thereby facilitating timely access to products and minimising compliance costs and other impediments to the choice of, and equity of access to, therapeutic products.***

As it stands, the Bill misses the opportunity to create a regime that builds on the current process to develop a scheme based on internationally recognised definitions and procedures, a scheme that would improve New Zealanders' access to the latest technology, and ensure the quality, safety and in-market performance of medical devices supplied in New Zealand in a cost-effective way.

The definition of a medical device itself is problematic: for example, it does not differentiate between General Medical Devices and In-Vitro Diagnostic (IVD) Medical Devices, two very different types of device that the current regime treats very differently. These definitions do not accord with those used by other regulators (such as the TGA and the FDA) or by international organisations. Similarly, the Software as a Medical Device definition is too broad and does not necessarily reflect current global thinking regarding clinical and technical considerations.

This lack of harmonisation is likely to negatively affect New Zealanders' choice of, and access to, therapeutic products.

95 percent of medical devices currently available in New Zealand are imported. If the proposed new Regulator requires additional or differently formatted data to that required in other markets, overseas-based manufacturers and importers are likely to cease supplying the small New Zealand market, rather than undertaking the work required to meet a set of requirements that apply only to this country.

Sponsors are not currently required to pay any fees to notify a device to the WAND database. The proposed new regime, which is considerably more elaborate, will cost more to operate and to maintain; the Bill, and the accompanying Treasury Regulatory Impact Statement, proposes these costs should be recovered at least in part from sponsors.

Therefore, even where a sponsor is able to satisfy the Regulator that a device meets the necessary criteria for authorisation, the increased costs in relation to NZ's market size will make the expected return on investment less attractive. Again, **the very real risk is that overseas-based suppliers will bypass this market, reducing the number of devices available in New Zealand. Inevitably, this will mean less choice for medical providers and poorer outcomes for their patients**.

Where a device does come onto the market, the increased costs will ultimately be borne by the taxpayer and by people who need to use the devices, reducing equitable access.

This could be largely avoided by requiring, rather than permitting, the Regulator to give due consideration to the evaluations and decisions of equivalent entities, such as the competent regulatory authorities in Australia, the US, the EU, and the UK.

Doing so would also permit a more effective transition from the current regime – particularly for devices that are currently available in New Zealand.

Transitioning to a new regime

- ***ATSNZ recommends that all medical devices notified to the WAND database be granted market approval, thereby eliminating the reassessment of some 250,000 devices already used safely and effectively in NZ. (This would not prevent the Regulator from auditing particular devices or categories if it chose to do so.)***

Schedule 1 of the proposed Bill allows for the creation of temporary market authorisations to cover medical devices currently available in New Zealand. Depending on the device's status, these authorisations remain valid for either six months, three years, or five years. These timeframes are impractical given the large number of devices currently in the market. Little thought seems to have been given to the practical issues generated by imposing a more onerous regime for regulating medical devices.

As the WAND database is not presently searchable, it is difficult to accurately calculate how many devices are available in New Zealand; however, the Australian Register of Therapeutic Goods (ARTG) contains some 62,000 entries for different types and categories of medical devices, and it is certain the number of medical devices available in New Zealand far exceeds the number of medicines in the market.

A shift from a self-regulatory environment, where all medical devices imported or manufactured in New Zealand are notified to the WAND database, to a system where market authorisations are required for all medical devices, will require significantly greater resource. The likely outcome is significant delays in the approval process and consequently, in the availability of medical devices to patients.

Currently Medsafe operates with about 60 FTE. Medsafe's 21-22 performance report sets out how time frames for lower risk products (OTCs) applications are seriously inflated when compared to their target timeframe and the timeframes achieved by regulatory agencies in Australia and the UK.

In the European Union, reassessing all medical devices to comply with new EU Medical Device Regulations has resulted in up to three years delay for existing devices, causing supply shortages and the withdrawal of devices from the market.

In addition to the extra requirements imposed on the sponsor of a device, **the Bill in its current form also includes strict licensing requirements across the supply chain. These requirements, as well as the requirement for a market authorisation will significantly affect choice of, and equity of access to, therapeutic products and stifle innovation.**

These same questions also apply where importation and distribution are on a larger scale. Rather than requiring wholesalers, third party logistics providers and other parties across the supply chain to be licenced, product safety could be ensured more effectively and efficiently by leaving the responsibility for the product throughout its lifecycle with the sponsor. The sponsor in turn could manage their risk and incentivise proper behaviour by their supply chain partners via legal contracts, as is currently done.

Concluding comments

ATSNZ is disappointed by the brief time allocated for consultation on the proposed Bill. While we and other stakeholders were given the opportunity to comment on an exposure draft of an earlier version of the Bill, this current version is substantially changed – sufficiently so to justify giving us and other interested parties the opportunity to work with officials on a revised exposure draft.

That process would have produced a more considered outcome and better alignment with the Bill's stated objectives. **Rather than building on the current regime, which has proven effective at facilitating equitable access to medical devices with minimal risk to patients and others, this bill proposes a regime that may put that at risk.**

Furthermore, the approach fails to reflect the different characteristics of various classes of medical device, in particular their varying risk profiles.

As a result, **this Bill does not promote an approval regime based on a rational calculation, that assesses the potential risk posed by a device, the benefits provided by that device, and the mechanisms needed to ensure public safety, while facilitating good health outcomes in deciding how the distribution of any device might best be managed.**

By passing up the opportunity to align the approach taken to regulating medical devices with the approach taken by our main trading partners, the Bill, if enacted, would close New Zealand off from the latest international innovations in medical technology, thereby creating less equitable outcomes for New Zealanders and a less efficient market for both suppliers and users of these essential healthcare items.

The following table sets out in more detail our concerns with the clauses in the Bill as it stands, and recommendations for how they might be redrafted.

Clause	Issues	Recommendations
24 – definition of a medical device	Fails to distinguish between General Medical Devices and In Vitro Diagnostic (IVD) Medical Devices, thereby eliminating the opportunity for different rules for what are very different types of devices. (IVDs are currently exempt from mandatory notification to WAND.) Not well aligned with the definitions used by competent authorities (TGA, FDA).	Define GMDs and IVDMDs separately. Use definitions that are aligned to a globally recognized standard, such as the World Health Organization or the International Medical Device Regulators Forum (IMDRF).
46 – remanufacture of medical device	Subclause (2) allows a person to repair, maintain or update a device that is intended to be used, but does not require them to do so in accordance with the standards or instructions of the responsible manufacturer.	Insert a provision that any repairs, maintenance or upgrade not carried out in accordance with the responsible manufacturer's standards or instructions will constitute remanufacture, regardless of whether that has

		resulted in a major change (as per subclause (3))
67 – a person must not (a) import or supply a medicine or medical device unless it has a NZ authorisation	A one-size-fits-all approach that is very much based on the current approach to regulating medicines and completely ignores the different characteristics of medical devices. This does not promote an approval regime based on a rational calculation that assesses the potential risk posed by a device, the benefits provided by that device, and the mechanisms needed to ensure public safety while facilitating good health outcomes in deciding how the distribution of any device might best be managed.	Replace the need for NZ authorisations with a notification regime that incorporates greater penalties for non-compliance and a searchable database.
or (b) export a medicine or medical device unless it has a market authorisation	The Bill means that there will be two sets of requirements for exporters to meet, rather than just the one from the export market.	The export authorisations should not apply where a medical device is being exported to a market that has stringent quality management systems and other checks.
119 – evaluation of medicine or medical device	Subclause (2) currently says 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.	Add to subclause (b) "*including evaluations and regulatory decisions made by other competent regulatory authorities."* to promote consistency with recognised competent authorities.
121 – criteria for sponsor of medicine or medical device	Ambiguity over how many sponsors can be granted market authorisation for a particular device. A change from the current regime, which permits multiple sponsors, could affect access to devices. Parallel imports without the sponsor's consent (possible under a licence) would likely make it much harder for the Regulator to maintain an effective post-market surveillance regime.	Ensure legislation explicitly allows for multiple sponsors.

	Where there is more than one importer of the same medical device, the current system requires each importer to notify that medical device to the WAND database. If multiple sponsors are not permitted, how would the single sponsor be chosen? How would a transition be affected?	
129 – major change results in different product	Definition of major change is unclear. Requiring a new market authorisation will likely trigger downstream requirements, for example adjustments to supply contracts. The rationale for this provision with respect to devices is unclear. Under current regulations, if a particular sponsor is the sponsor of two or more medical devices, it is in many cases only necessary to enter information in respect of each kind of device (instead of in respect of each device) for which the sponsor is responsible. This would be a significant departure from what is common practice in comparable regulatory regimes.	Regulations will need to clearly set out the definition of what constitutes a major change. This definition should be determined from the perspective of the end-user, with a focus on risk. For imported devices, require the Regulator to give weight to decisions taken in the country of origin and by other competent regulatory authorities in determining whether a new market authorisation is required. Where the change is to a matter or information relating to the product and the physical product has not itself changed, allow the Regulator to vary the existing authorisation
134 – a market authorisation cannot be varied to cover a product after a major change	Definition of major change is unclear. Requiring a new market authorisation will likely trigger downstream requirements, for example adjustments to supply contracts. The rationale for this provision with respect to devices is unclear. Under current regulations, if a particular sponsor is the sponsor of two or more medical devices, it is in many cases only necessary to enter information in respect of	Regulations will need to clearly set out the definition of what constitutes a major change. This definition should be determined from the perspective of the end-user, with a focus on risk. For imported devices, require the Regulator to give weight to decisions taken in the country of origin and by other competent regulatory authorities in determining whether a new market authorisation is required.

	each kind of device (instead of in respect of each device) for which the sponsor is responsible.	Where the change is to information relating to the product and the physical product has not itself changed, allow the Regulator to vary the existing authorisation.
4 – sponsor must notify regulator of any minor changes	The Bill defines a minor change as any change that is not a major change. This definition seems to create a requirement for notification that is not proportionate to the potential risk of a minor change. The likely number of notifications would exceed the Regulator's capacity and create significant access issues.	Regulations will need to clearly set out the definition of what constitutes a minor change. Requirements to notify the regulator should be based on an assessment of potential risk, rather than being an automatic obligation.
Part IX, Subpart 2 – cost recovery	Clause 335 requires that the costs of administering the Act that are not provided for by money appropriated by Parliament for that purpose be recovered by way of fees, levies, or otherwise. Clause 338(3) allows the Regulator to make up any shortfall in cost recovery during the preceding four financial years potentially requiring one group of applicants for authorisation to subsidise another.	Industry should be required to fund only transaction costs, such as the costs of approval, accreditation, and certification activities, as well as audits of individual businesses and post-market surveillance. The Crown should be required to fund all public good activities including policy advice, legislative development, international engagement and cooperation, guidance, development of export standards, investigations and enforcement action including prosecutions, as well as the costs of establishing and maintaining the assets and infrastructure the proposed Regulator would need to function. Cost-recovery settings should be reflected in legislation, with specific fees and charges developed in consultation with industry stakeholders and implemented by regulation. These regulations should include agreed service levels used to assess the performance and condition of the regulatory regime by the DG of the MoH.

346 – regulator may rely on decisions etc of recognised entities	This does not require the Regulator to consider relevant decisions made by other competent entities.	Replace with "*the regulator must have regard to and may rely on decisions etc of recognised entities*".
363 – the Regulator must maintain a therapeutic products register [that] must include (a) all therapeutic products (i) that have a market authorisation; or (ii) for which an application for a market authorisation has been made but not yet determined; or (iii) for which a market authorisation has been refused.	There are commercial-in-confidence implications with publishing when a market authorisation has been made but not yet determined, and implications for potential Sponsors where an authorisation has been refused. These requirements would be better captured in secondary legislation to allow for more detailed consultation on the implications of these decisions being made public. As a result, Sponsors may opt not to proceed with an application or to delay submission, thereby limiting New Zealanders' choice or timely access to medical devices.	The Regulator's obligations with respect to the maintenance of a register should be detailed in secondary legislation; along with a mechanism allowing for consultation on whether a decision should be published.
Schedule 1 Transitional, savings, and related provisions, in particular clauses 10 – medical devices listed under 1981 Act: temporary market authorisation created and 11 – unlisted medical device or unregulated product and now medicine or medical device: temporary market authorisation created, also clauses 5, 27	The time for which temporary authorisations remain valid severely underestimates the work required to assess all devices currently in market. The Australian Register of Therapeutic Goods contains some 62,000 entries for different kinds and categories of medical device.	Consultation with sector to determine how market authorisations could apply to types and categories of device rather than individual devices. Autonomous recognition of approvals by other competent authorities, such as but not limited to EU, UK, US, Australia, Canada, Japan.

Appendix One

Overseas evidence that should be considered:

Specific evidence and documentation, issued by specific overseas regulators and assessment bodies, should be considered by the New Zealand Regulator:

- Australian Therapeutic Goods Administration (TGA)
- Certificates issued by Notified Bodies designated by the medical device regulators of European member states, currently under the three Directives on Active Implantable Medical Devices (AIMD), Medical Devices (MDD) as well as In Vitro Diagnostic Devices (IVDD) *To be replaced by the Medical Device Regulations (MDR) and In Vitro Diagnostics Regulations (IVDR)*
- Decisions of the United States Food and Drug Administration (FDA)
- Approvals and licences issued by Health Canada
- Pre-market approvals from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA) or Registered Certified Body (RCB), whichever is applicable)
- Certificates and reports issued under the Medical Device Single Audit Program (MDSAP).
- ISO 13485:20016 and ISO 9001:2015

The documentation should be issued by an overseas regulator or assessment body for the same (design / intended purpose) medical device when applying for registration in New Zealand.