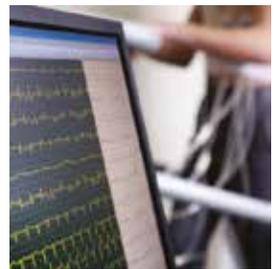


**medical technology**

ASSOCIATION OF NEW ZEALAND

# Australia New Zealand Therapeutic Products Agency **ANZTPA**

A proposed regulatory framework for medical devices



“Medical device regulation should ensure acceptable patient safety standards while maintaining timely access to innovative technologies.”

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## **Who is MTANZ?**

The Medical Technology Association of New Zealand (MTANZ) was first established in 1979 and is the only industry body representing medical technology manufacturers, importers and distributors of medical devices in New Zealand.

Medical technology covers a wide range of products used in the diagnosis, prevention, treatment and management of disease and disability. These products include everything from familiar items like syringes and wound dressings to sophisticated MRI scanners, pain management devices and customised titanium implants.

The purpose of this MTANZ document is to outline the key issues that stakeholders should consider and to offer some possible solutions to create a workable ANZTPA model that will support safety, innovation and cost-efficient compliance.

## **What is ANZTPA?**

The Australian and New Zealand governments have agreed to form a single trans-Tasman agency, the Australia New Zealand Therapeutic Products Agency (ANZTPA), to regulate therapeutic goods (i.e. medicines and medical devices). This agency will eventually replace the Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand.

What are the ANZTPA regulations and why are they being introduced?

One of the stated aims of the proposed joint regulatory scheme for therapeutic products under the ANZTPA is to assure the safety and satisfactory performance of medical devices used in Australia and New Zealand. It is proposed that these new regulations will come into effect by July 2016.

# MTANZ SUPPORTS SAFETY AND PERFORMANCE

MTANZ wholeheartedly supports the need for medical devices in New Zealand to demonstrate that they meet an internationally recognized standard for safety and performance. The health and safety of the New Zealand public remains our highest priority.

MTANZ believes improvements may be gained under ANZTPA with five principles to guarantee timely access to safe medical technology while supporting innovation:

1. a regulatory scheme based on international best practice
2. a regulatory scheme that recognises third-party conformity assessment for all classes of medical devices
3. a regulatory scheme with a fee structure that is limited to efficiency costs only and fairly reflects the market size
4. a regulatory scheme that has a major focus on post-market vigilance and surveillance
5. a regulatory scheme that fosters and supports innovation and does not severely lengthen time to market.

## We support:

- a pre-registration process prior to marketing a medical device to ensure quality assurance for the benefit of patients
- recognition and use of internationally-recognized pre-market regulatory clearance
- a robust post market surveillance process to maintain public health and safety
- ANZTPA operating cost-effectively, being accountable and transparent.

## We do not support:

- Allowing the potentially unlimited cost of the full cost-recovery system – a system that will be fully funded by industry.

## 1. A regulatory scheme based on international best practice

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MTANZ believes ANZTPA should adopt the Global Harmonization Task Force (GHTF) Essential Principles of safety and performance and the International Standards Organization (ISO) 13485 standards rather than developing our own unique principles.

All imported devices with CE and FDA clearance have already attracted significant costs for regulatory approval to market in international markets and this cost is factored into the price to New Zealand buyers.

MTANZ believes it is imperative that ANZTPA does not duplicate what is already being undertaken by an internationally recognized regulator, but draws on the European or US expertise to ensure safety of devices entering the domestic market.

**Products that can show CE certification or FDA clearance should not be expected to repeat the process under ANZTPA and spend an additional \$100,000+ on compliance to enter a significantly smaller market. This spend would filter to increased healthcare costs for the NZ purchaser.**

ANZTPA follows the European model using 'competent authorities'. This model historically works well and uses resources and expertise of registered third party reviewers (Notified Bodies) efficiently and effectively.

The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK is an example of a national competent authority which accepts Notified Body review and clearance of products.

Under this system ANZTPA would be in a monitoring and standards role rather than duplicating the work of Notified Bodies and adding layers of bureaucracy that offer limited, if any, additional safety guarantees.

By separating regulator and evaluator roles ANZTPA could free up resources from pre-market scientific and technical assessment to concentrate on post-market surveillance and vigilance.

Proposed reforms to the European regulatory system are underway and this must be factored in to the establishment of ANZTPA to avoid duplication. The work of the International Medical Device Regulatory Forum (IMDRF) is undertaking several projects that can contribute significantly to the ANZTPA Rules.

ANZTPA must strive to remain aligned to international best practice and not introduce local, unique requirements. These requirements would add complexity and cost without delivering additional gains in health outcomes.

# The MHRA ensures medical devices work and are acceptably safe:

- enforces regulations by investigating allegations received about possible non-compliance with the regulations; operating a proactive inspection programme where manufacturers are audited annually by their Notified Body to maintain ISO certification
- designates UK Notified Bodies and audits them
- investigates post-market surveillance reports received from device manufacturers, users and the public
- maintains a register of manufacturers.

## 2. A regulatory scheme that recognises third-party conformity assessment for all classes of medical devices

MTANZ believes the recognition of third party conformity assessment under ANZTPA is essential for all classes of medical devices.

The global market is the primary focus for New Zealand device manufacturers with audits undertaken by reputable European Notified Bodies for conformity assessment in the European market and FDA clearance for entry into the US market. The proposed ANZTPA should not become both regulator and evaluator of devices, an apparent conflict of interest and a virtual monopoly position. Requiring domestic manufacturers to be audited by ANZTPA will

result in additional cost with no added value and a certification with no international recognition.

Specialised expertise is required to audit the product design, safety and manufacturing processes of high risk medical devices. This audit expertise is limited internationally and even more so in New Zealand and Australia. If ANZTPA requires review of Class III device submissions for pre-market clearance, considerable cost and time will be added and NZ companies may be forced to remove the device from the domestic market and only manufacture the device for export.

- ANZTPA should recognise conformity assessment from third parties for domestic manufacturers in order to issue an ANZTPA registration and clearance.
- ANZTPA should publish a list of European Notified Bodies and accredit these bodies to audit and issue conformity assessment certification acceptable to ANZTPA.
- ANZTPA must accept unilateral recognition of international regulatory conformity assessment and avoid local unnecessary and costly delays for patients to access life-prolonging and saving technology.



### 3. A regulatory scheme with a fee structure that is limited to efficiency costs only and fairly reflects the market size

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If ANZTPA is allowed to recover whatever costs it incurs from industry it may threaten the viability of smaller companies in New Zealand. It will definitely affect the availability to patients of innovative, new technology devices being developed by smaller companies within and outside of New Zealand.

A report on the Joint Therapeutic Agency Industry Funding Issues<sup>1</sup> by Bryce Wilkinson of Capital Economics Limited in 2004 concludes that: “The major arguments against full industry funding ... relate to the general problem of excessive costs in relation to benefits under a

statutory monopoly with mandatory purchase.” He argues this is a “recipe for cost excesses and mediocre performance.”

His solution is to introduce competition where possible and to ensure that costs are related to efficient cost and marginal benefit – the lowest cost that the service can be provided under an efficient system.

MTANZ believes charges and fees must be proportionate to sole, single country approval holders and reflect the smaller New Zealand market.

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<sup>1</sup> Wilkinson B. Capital Economics Limited. Joint Therapeutic Agency Industry Funding Issues Report December 2004. p18, p25.



#### **We recommend:**

- a regulatory scheme with a fee structure that is limited to efficiency costs only and fairly represents potential market size
- funding for ANZTPA should be transparent, fair and appropriate
- sources of funding should be diverse and primarily based on normal budgeted revenue from Parliament, and there should not be automatic access to industry funding revenue
- funding should appropriately reflect the respective market size, and be affordable for the sole, single country approval holder
- a review of the model that uses GMDN codes for attributing charges and fees when the best model is still device class.

#### **We do not support:**

- the intention for industry to fully fund ANZTPA on the basis of full cost recovery without strict performance requirements in place
- a fee structure which is outside the cost benefits to the manufacturers in comparison to the potential market size.

## Governance issues for consideration:

- efficiency measures used to assess the impact of ANZTPA including benchmarking market research and market testing third-party competition
- ANZTPA will need to operate through a consultative committee that encompasses stakeholder representation, an independent chair, an ability to monitor agency efficiency, access to adequate information and transparent reporting processes
- independent reviews of industry funding arrangements and independent dispute resolution processes be established
- measurable performance targets for ANZTPA's service provision, including consideration of penalties for non-performance
- ANZTPA's charging activities should be subject to the competition laws in Australia and New Zealand aimed at preventing the abuse of a dominant position
- ANZTPA should be able to demonstrate that the charges largely have the un-coerced consent of those being charged.



## 4. A regulatory scheme that has a major focus on post-market vigilance and surveillance

The current regulatory framework for medical devices foresees that once a medical device is placed on the market, vigilance and post-market surveillance systems have to be put in place by manufacturers and regulators.

Both the European and US regulatory systems clearly define these requirements. The systems allow for rapid identification and response in case of incidents which may put patients, users or the product performance at risk.

A better defined legal and regulatory framework on vigilance and greater harmonisation of post market surveillance activities is needed to ensure rapid and consistent Australasian-wide risk identification and response. This would deliver significant benefits for overall patient safety and

demonstrate better use of resources than duplicating pre-market assessments.

ANZTPA must appreciate that there is often a lack of pre-market evaluation data for medical devices and that randomized control trials for medical devices are not always appropriate or ethical. In addition, the review of medical device submissions can never identify all potential product design or process issues affecting safety and performance.

There is a reliance on post-market data collection and health economic data collection for medical devices once the product has been in clinical use. Post-market surveillance has historically proven to be an effective monitoring system in the major international markets.

## MTANZ supports the establishment of a trans-Tasman adverse reporting and early warning system.

- MTANZ supports the need for suppliers to actively engage with ANZTPA and to collaborate in all recalls and field corrections when a device poses a safety risk to patients, users or the public.
- Pre-market testing and submission review cannot fully mitigate the safety risk of medical devices. We therefore advocate a clearly defined process for post-market vigilance and surveillance be initiated and monitored.
- Risk management must be balanced with the clinical benefits to patients of innovative medical devices being brought to market in a timely manner.

## 5. A regulatory scheme that fosters and supports innovation and does not severely lengthen time to market

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MTANZ supports the need for medical devices to be regulated to ensure acceptable safety and performance. **Regulation must, however, be balanced with the need to create an operating environment that fosters and supports innovation and clinical benefit.**

ANZTPA must support the innovation lifecycle of medical technology which is often as short as 18 months – 2 years. The registration process must be undertaken in a concise and timely manner to reflect the short lifespan of many innovative devices.

The ability to innovate is critical for the medical technology industry in New Zealand to remain competitive and continue to bring valuable contributions to efficient and high-quality healthcare.

Emerging medical technology companies in New Zealand have already demonstrated they can

develop innovative devices that can compete on world markets if given the right support and encouragement.

To maximise this export opportunity, New Zealand firms must be allowed to use suitably-qualified third-party conformity assessment bodies for all classes of devices to ensure best access to international expertise and markets. Their key export markets expect this certification and it would be onerous to expect manufacturers to duplicate pre-market assessment for certification that has no value in export markets.

**The proposed ANZTPA must support innovative development of medical devices in New Zealand and avoid higher costs and longer product to market time compared to those experienced by device manufacturers in Europe and the US.**

### What kind of regulatory system do we want to achieve?

Industry wants a clear, predictable and effective regulatory system specifically tailored for medical devices that ensures:

- The highest level of safety for patients
- Timely access to the latest, innovative technologies
- The trust of its stakeholders
- The sustainability of national healthcare systems
- Keeps R&D and innovation in New Zealand.

### Medical technology sector in New Zealand

- Medical equipment accounted for around \$642 million in exports to June 2012 and is currently showing a compound annual growth rate of 5 percent.
- The sector grew by \$260 million in the period 2001-2011.
- Employment in this sector has also grown to 2,940 people from 1,610 in 2002.
- The sector export revenue is expected to double within the next 3-5 years to \$1.2 billion.
- The sector spent more than \$66 million on R & D in 2012.



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