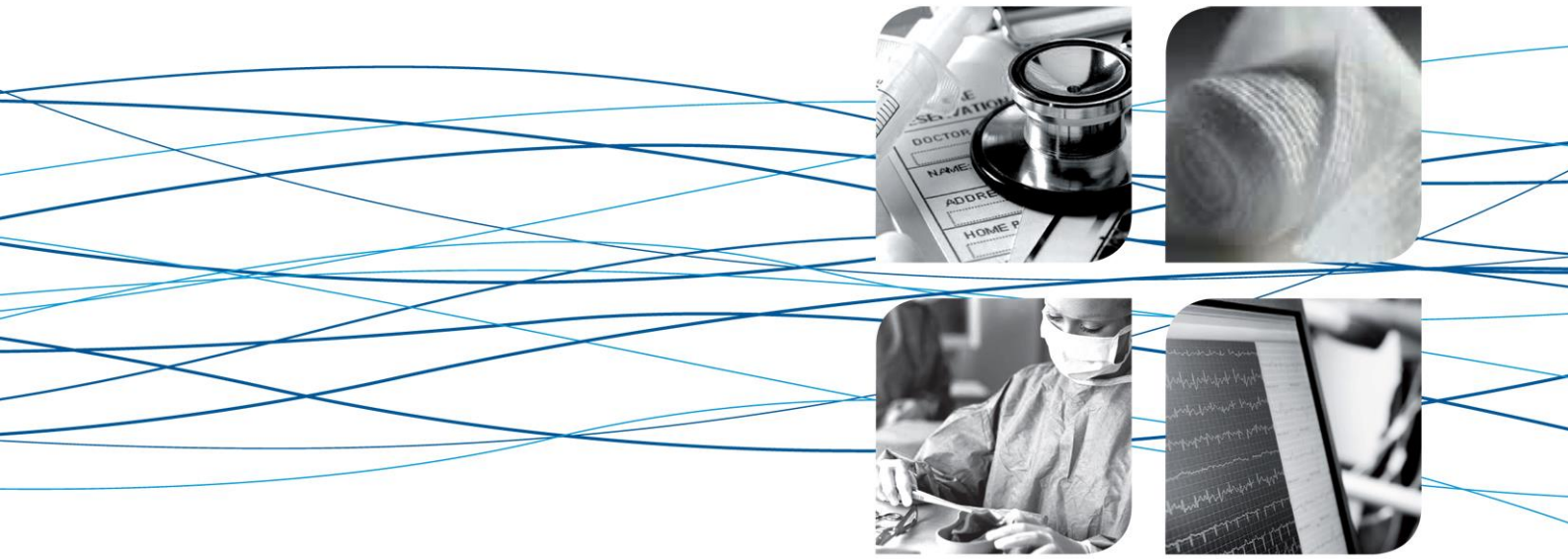

Medical Technology Association of New Zealand Submission

For

New Zealand Therapeutic Products Regulatory Scheme Consultation

April 2019

medical technology
ASSOCIATION OF NEW ZEALAND

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Introduction

On December 14, 2018 the New Zealand Ministry of Health (MoH) published a draft Therapeutic Products Bill[1] intended to replace the Medicines Act 1981 and establish a new regulatory scheme for therapeutic products.

The Medical Technology Association of New Zealand (MTANZ) wishes to submit comments on the proposed Bill as a representative of the medical technology industry sector. MTANZ is the only industry body representing medical technology manufacturers, importers and distributors of medical devices and was first established in 1979. MTANZ is a strong supporter and representative of New Zealand researchers and manufacturers in the development of medical devices for international markets.

An overarching comment is that the proposed Bill is very complex, and in some parts appears to be written, both in intent and with language / terminology, specifically for the regulation of medicines. Further, it appears the regulation of medical devices have then been force fitted into this scheme and so are in fact being treated as medicines. There is a plethora of significant differences between medicines and medical devices and, if the MoH has a desire to effectively regulate these different therapeutic products effectively, there needs to be recognition of these differences within the Bill.

MTANZ would like to respectfully suggest the following "**Parts"** are separated into industry sectors to better reflect requirements for each specific sector e.g medical devices

Part 3 Dealing with therapeutic products
Part 4 Product approval
Part 5 Licences and permits

The medical device sector of the Bill also needs to specifically recognise the sub-sector of *In Vitro* Diagnostics (IVDs) and refer to specific requirements for these medical devices. This should absolutely include laboratory manufactured, "in-house" IVDs that do effectively have the same (or higher) level of risk associated with them as do IVDs that are offered commercially. To not have legislation that covers in-house IVDs automatically sets an unacceptable and uneven playing ground.

The Bill uses, in many instances, New Zealand specific terminology that needs to be aligned more with globally recognised medical device terminology to avoid confusion of definitions. The New Zealand medical technology industry is well integrated and reliant on the international medical technology community and therefore, the Bill should be more cognisant of utilising global terminology to support harmonisation.

[1] NZ Ministry of Health, Therapeutic Products Regulatory Scheme consultation, accessed 8 April 2019: https://www.health.govt.nz/publication/therapeutic-products-regulatory-scheme-consultation

The expectation is that the Regulator will have tested and confirmed the usability and reliability of the new, established electronic system to ensure it has the capacity and capability to accept and process the considerable data that will be expected to be entered at the commencement date of the regulatory scheme. This requirement is essential for the industry to have confidence in the establishment of the New Zealand regulatory scheme

The rigour of regulations must be balanced with the need for patients to be able to access new breakthrough technologies in a timely manner. The regulatory and compliance cost must reflect the small New Zealand market

Response to the Therapeutic Products Bill April 2019

Chapter A

A1 Do you support the general design of the new regulatory scheme for therapeutic products?

2 Partially support

The consultation document, in relation to medical devices state "…the intention is to apply the full range of pre- and post-market controls in accordance with the risk-based model…", yet the model discussed which does not see the Regulator having the ability to conduct conformity assessments does not allow pre-market controls at anything bar a verification level.

Rather the stated intent is to leverage international approvals. If this is the case, then it would be better to require New Zealand sponsors to "declare" compliance with the requirements of the jurisdiction that's being leveraged and where relevant provide evidence of same? Not all jurisdictions have the same GHTF requirements. The proposed regulatory framework has classification rules and essential principles, however, will be no way to determine compliance with these, having classification rules and essential principles that are unique to New Zealand will also artificially limit the ability of the new Regulator to leverage international principles.

The Medical Technology Industry supports the Regulator recognising 3rd party conformity assessment and not undertaking this activity in New Zealand by the Regulator.

The Medical Technology Industry is concerned there has been no decision regarding the governance of the new Regulator and that it could be established as a Crown Entity, a departmental agency or part of the Ministry of Health. How the new Regulator is set up will have considerable impact on the industry and the fees and charges collected to support the activities of the Regulator. It is not intended to consult with industry as to how the Regulator will be established but the industry needs to be assured the new Regulator will be efficient with the ongoing operations being transparent and accountable to the industry.

The cost of the establishment of the Regulator must be funded by central Government.

Chapter B

Part 1: Preliminary provisions

B1 Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).

The Medical Technology Industry supports the purpose and principles of the Bill and, the need for co-operation with overseas regulators. It is essential to align devices (both import and export) and avoid costly duplication of conformity assessment and delayed availability of devices in New Zealand.

The new agency should be established as a Regulatory Authority.
The regulatory authority is in control of two main elements:

i. Firstly, they set the public safety requirements and intervention mechanisms and
ii. Secondly, they can select, international pre-market approval bodies to do the technical and scientific review

Ultimate control remains under the jurisdiction of the Regulatory Authority.

Overseas evidence that can 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, under the under the current 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), whatever 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

(4) Principles guiding exercise of powers under this Act

The Regulator's use and choice of tailored and responsive regulatory tools must be made fairly and must be an appropriate response to a given situation. There should be included a reference made to decisions being made *fairly* and meeting *rules of natural justice*

Part 2: Interpretation

B2 Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50).

21 Meaning of a medical device.

Definition needs to completely align with the harmonised global definition.

GHTF/SG1/N29:2005 *Information Document Concerning the Definition of the Term "Medical Device"* (under revision).

The definition of a medical device within the Bill does have the potential to exclude some IVD medical devices. While IVD medical devices are a sub-set of all medical device, to avoid potentially excluding some IVD medical devices from the operation of the Bill, a specific definition of IVD medical devices should be included within the Bill itself. The definition used should align with the harmonised global definition for IVD medical devices.

Regardless of the definitions enacted the regulator needs to maintain flexibility to recognise different classifications from different jurisdictions in respect to products that sit on the borderline between medicines vs devices (i.e some products are treated as medical devices in some jurisdictions and medicines in others: international approvals should be leverageable in New Zealand despite these differences)

34 Meaning of manufacture, for medical devices

The definition of "responsible manufacturer" for a medical device (Section 31(5) of the Bill) doesn't align with the new European Medical Device Regulations (MDR):

'manufacturer' *means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.*

"Responsible manufacturer" is a medicine terminology. Regulatory nomenclature should have recognized international universal terminology "**legal manufacturer**" for medical devices

(4) Remanufacture

This covers refurbishment, reprocessing and rebuilding activities that produce a device significantly different from the original, or that are carried out on devices intended for single use only.

Therefore, the "remanufactured" medical device must meet the original manufacturer's specifications and will require a new product approval from the agency. Who is responsible for ongoing service and maintenance if required?

43 Meanings of wholesale supply and non-wholesale supply

From this definition a medical device supplier could be classified as both a wholesaler and a non- wholesaler by means of supplying a device as per (2) (a) *to supply to other persons* and (3) *supply to patients*
The medical technology industry rejects the concept of defining medical device sponsors as either wholesalers or non-wholesalers – this is more appropriate for medicines A medical device "product approval" should allow the sponsor to conduct all supply chain activities without further regulatory requirements

"Supply restrictions in use" needs more clarification with respect to medical devices as concept more related and utilised for medicines.

Part 3: Dealing with therapeutic products

B3 Please provide any comments on the product approval controls (ss 51 and 52).

52 Sponsor's consent required to import an approved product
(1) (b) import the product without the written consent of the sponsor

While addressing the concerns relating to parallel importing of products, there are situations where there are multiple importers of the same product e.g gloves and dental micro brushes. Who would be recognised as the Sponsor from whom all other suppliers require written permission to import the product? From the definition of "Sponsor" this would be the person to whom the approval was granted (and there could be more than one Sponsor for the same product).

All Sponsors should maintain evidence of direct relationship with the manufacturer, especially where there are multiple importers/ Sponsors of the identical product from the same manufacturer.

B4 Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).

55 Persons in supply chain must comply with regulations.
(1) (d) "disposal of therapeutic products"

This will need some detail as to the extent of complying with this requirement for medical device suppliers. This has more relevance to medicines than devices.

B9 Please provide any comments on the authorisations for veterinarians and veterinary staff (ss 66–70).

To avoid confusion, it would be better to refer to the customer of the veterinarian as an "animal" rather than a "patient"

68 Veterinarians: wholesale supply
(a) the regulations permit the device to be supplied

Devices approved for humans aren't always approved for animal use. As soon as you decide to use a therapeutic product on an animal it inherently becomes a non-therapeutic product. And, if it is approved or approval exempt, it automatically becomes unapproved.

The veterinarian takes the risk associated with use of the product post market. Sponsors cannot be held responsible for the use of their approved products in veterinary animal health.

77 Patient of carer importing a medical device for personal use

There needs to be an additional cause inserted:
"*The imported medical device doesn't exceed indicated usage for personal use with an appropriate limit on volume"*

B11 Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.

75 Manufacturer of custom-made devices

Custom-made devices need to be defined according to IMDRF definitions. This definition should be included in the Bill.

B12 Please provide any comments on the offences created in sections 81–94.

82 Meaning of advertisement and related terms

(1) This should state that it excludes Healthcare Professionals

87 Notifying Regulator of suspicion of tampering
(2) (b) the therapeutic product does not yet exist.

This statement needs better clarification with examples

88 Misrepresentation about therapeutic product

How can you misrepresent a therapeutic product when the product involved in not a therapeutic product?

92 Misleading information in records

A "required record"? This should be defined in regulations.

Part 4: Product approval

B13 Please provide any comments on the sections covering product approval requirements (ss 94–104).

95 Criteria for product approval

Products manufactured in New Zealand that are only intended for supply in overseas markets would still require a product approval. This requirement should only attract a simplified pathway that meets the regulations of the importing country

96 Product standards
(1) The rules may specify standards for therapeutic products
As medical devices will be approved in New Zealand recognising international regulatory authorities pre-market approvals, no standards should be mandated in legislation for medical devices approved in New Zealand

Where the regulator may specify a standard for a medical device the Medical Technology Industry supports direct adoption of international standards and AS/NZS direct adoptions of international standards relevant to medical device safety and performance

The Medical Technology Industry supports the intention to adopt the internationally recognised Unique Device Identifier (UDI) as a means of global harmonisation for medical devices. In doing so though it is critically important, specific labelling elements that do not exist in implemented UDI schemes in jurisdictions such as the EU and the USA are not introduced for New Zealand

98 Content of approval
(e) name of the responsible manufacturer and the address of each place at which it manufacturers the product

This requirement will be impossible to comply with for device manufacturer because there are frequently multiple global sites for a manufactured device. This requirement is more suited to manufacture of medicines.

Difficult to maintain and unnecessary as legislation will already require maintenance of evidence of conformity assessment, e.g. critical manufacturing sites have already been assessed and improved by the recognised overseas pre-market approval

99 Scope of approval

For medical devices this doesn't seem to work as it's talking about an individual product as opposed to a number of grouped devices., as such it's more specific for medicines

100 Major changes result in a new product

These clauses refer to medicines more than medical devices. For medical devices any change, whether major or minor change should not need to be notified to the New Zealand Regulator if the leveraged overseas pre-market approval does not change . The New Zealand Regulator should only receive notification in relation to elements that make up the content of approval, Section 98, and these notifications should not result in a new product approval.

101 (2) Minor changes

Refer to comments above

102 Change of sponsor

(2) The regulator may on application by the sponsor *and/or new* sponsor transfer an approval to a new sponsor….

(3) If the regulator is not satisfied with the new sponsor the regulator must refuse to accept the change in sponsor and *may cancel the approval of the medical device entries on the database*

Where the business has been divested, if the Regulator is not satisfied with the new Sponsor for any reason, the path forward for the Regulator would be to cancel the product approval

104 Approval lapses on deaths, bankruptcy, or insolvency of sponsor

(a)(ii) and (b)(ii) In bankruptcy or insolvency wouldn't it be better to treat registrations as assets (particularly for insolvencies, if the registrations lapse, the liquidator loses the ability to sell them to another sponsor). Product approvals should be treated as company assets.

The approval lapses on death, bankruptcy or insolvency of sponsor could result in critical device shortage. This clause needs to be re-thought in relation to medical devices.

108 Grounds to cancel approval
(a) the quality, safety, or efficacy or performance of the product for the purposes for which it is used *is unacceptable* should read "*becomes unacceptable*"

There is no process to suspend a product, only cancel. This means that the Sponsor may have a problem that needs fixing and can be fixed and then the Sponsor can continue supply. If the product approval is cancelled the Sponsor would need to apply again to the Regulator for product approval and this would result in more cost with new approval numbers and time to supply market again

112 Effect of cancellation

What happens to product that is in the supply chain at the date the cancellation has effect?

113 Therapeutic products register

(2) (b) therapeutic products that the Regulator has refused to approve

(c) therapeutic products for which an approval application has been made

Both the above clauses would be considered breaches of commercially sensitive information if published on a public website. The Medical Technology Industry rejects both clauses (b) and (c) as not being acceptable to the industry.

(6) The Regulator must make the register publicly available

The Regulator should only publish those parts of the register that are not commercially sensitive and suggest that there is a public and non-public section of the register.

B15 Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).

Approval exempt products should be defined in the regulations and reflect low volume, special populations or unique products.

B16 Please provide any comments on the sections covering sponsor obligations (ss 116–119).

116 (1)(c) Sponsor of approved product must ensure compliance with approval

If the Sponsor does not have a legal control over the "other person" how would the Sponsor ensure they do what they're supposed to do? Does this extend to ensuring the healthcare professionals are using the product as intended? If so, such a requirement would be overly onerous.

118 (1)(f) Sponsor must comply with regulations

"Adverse information" is referenced to medicines.

119 Sponsor not responsible for approved products imported without consent

This should include and extend to, products imported for personal use and approval exempt products.

Further, the Bill should clearly state that any entity that imports without the consent of the Sponsor is required to assume all the responsibilities that would otherwise be required to be met by the Sponsor, It is not adequate to rely upon the Regulator to add these responsibilities to the licence or permit as conditions.

Part 5: Licences and permits

B18 Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).

This section applies to medicines only. Medical devices should not be covered by licenses.

B20 Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).

131 What permits may authorise
(1)(a) import or supply a medicine, medical device, or Type-4 product without it being approved or import an approved product without sponsor's consent

Medical device suppliers will have concerns if an approved product is being imported into NZ without sponsor's knowledge. The Sponsor should be included to ensure awareness of product in New Zealand and batch numbers recorded for safety reasons Any supplier who does import/supply without the sponsor's consent has to carry all the obligations the Sponsor would otherwise be required to carry including the written permission of the manufacturer.

B21 Please provide any comments on the sections applying to licences and permits (e.g, those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).

This section would be better dealt with in regulations

136 Regulator may split application

This section is too complicated and needs better clarification.

137 Duration
(1)(b) remains in force for 3 years

In some circumstances, 3 years for a licence could be too short given that clinical trials can take longer to complete and reapplying for an extension of the licence would be counter-productive. It would make a lot more sense for the duration of a licence or permit to be determined as part of the evaluation process. The licence or permit should have an expiry date as established during the granting of the licence or permit of the regulator (1b and 2b).

B22 Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).

151 Death, bankruptcy, or insolvency of licence or permit holder
(4) A person to whom the licence or permit is transferred must notify the Regulator within 5 days

This should be **20 working** days especially if there has been a death of the licence holder.

A further clause (5) should be added to include: *if the licence or permit holder resigns and the licence or permit can be transferred to another employee who meets the required criteria*
In this situation wouldn't the legal entity hold the licence or permit?

This section treats licences and permits as property that can be transferred in these situations, yet for product approvals it is intended to automatically cancel them. And the same in reverse with transferring – you can transfer a product approval but not a permit or licence. Wouldn't it make a lot more sense to treat them all the same way? If you divest part of your Business you should be able to transfer all associated product approvals, licences and permits and in wind up or death situations everything is treated as property.

B23 Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).

154 Licensee must ensure health practitioner has authority and resources

The Medical Technology Industry rejects licences for medical devices and cannot ensure healthcare professionals/ practitioners have authority and resources. This is more reflective of medicine requirements.

Part 6: Regulator

B24 Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).

The Medical Technology Industry supports the focus of the Regulator on an active and comprehensive post-market monitoring programmes to collect information about the safety, quality and performance of medical devices after they have been approved. Any process and requirements must be aligned with current international practice and reflect the same language and interpretation of criteria.

161 Public safety announcements

There needs to be a requirement for consultation about such public safety announcements before they're made – the Regulator should not be able to unilaterally make such statements about such things without consultation and dialogue with the Sponsor

162 Recall order

There must be consultation / dialogue before a recall order is made. There also needs to be a mechanism, as there is now, for sponsors to initiate a recall action in consultation with the Regulator. A recall order should only be made in a situation where a sponsor is not willing undertake such an action under their own initiative and, after the appropriate dialogue, the Regulator has formed the view a recall is still needed.

B25 Please provide any comments on the regulator's investigative powers (ss 183–196).

185 Regulator may require information
(1)(b) in relation to a specified relevant document

Suggest inserting a time frame of **20 working days** to enable the sponsor to source any documentation required by the Regulator. Not all documentation is stored in New Zealand.

(2)(b) an offence against this Act has been, is being, or likely to be committed

There should be a requirement to specify what the offence is?

(2)(c)(i) should state what the risk is?

186 Testing of samples for investigative purposes

Any testing for investigative purposes must be in collaboration with the manufacturer.

187 Laboratories and analysts

If a New Zealand laboratory will be the mandated testing facility how will international manufacturers transfer the test methods to them and how will the New Zealand testing laboratory know they'll appropriately validate those methods. For some products there'll also be very specific equipment needed to do the tests; sometimes this equipment may be custom made for a specific device.

188 Imported consignments may be detained pending testing

(2)(c) – so what happens to it after 20 days? Is it just released by Customs?

B27 Please provide any comments on the review of regulator's decisions (ss 200–204).

200 Application for review of Regulator's decisions

Schedule 2 specified who's able to apply for a review. This should include: "…a person whose interests are affected by an initial decision…"
Schedule 2 also specified what decisions are reviewable but does not include approvals.

Addressing both comments above allows competitors (or even "affected" individuals of the public) to apply to have a decision reviewed.

(2)(a) The timeframe should be started from when the applicant has become aware of the decision not when the decision is made, and **90 working days** would be more appropriate than 30 working days

(2)(c) A review would generally only be required when the Regulator has made a mistake. As such there should not be a fee for this, if a fee is payable, should be refundable if the review is found in favour of the applicant

202 Procedure on review

There should be a mandated timeframe within which the review panel reaches a decision. The review panel should also be required to form its decision having a view to the Purpose and Principles of the Bill.

203 Decision on review
(2) the review panel must notify the applicant and Regulator of its decision

There should be a time frame identified from application to review and to the panel's decision and suggest **90 working days**

B28 Please provide any comments on the administrative matters relating to the regulator (ss 205–222).

208 Notice and reasons for decision by Regulator

(5)(b) What is "reasonable"? Language like this really shouldn't be in legislation as it's very subjective. Rather than being 'reasonable' there should be a time specified.

209 Sharing of information with regulatory agencies
(4) The Regulator must not give information to an overseas organisation unless satisfied that appropriate protections will be in place

An additional clause should be included to require the Regulator to communicate with the sponsor before releasing any information to an overseas organisation.

The whole of this section should be limited to overseas agencies the Regulator has a formal agreement with that specifically protects confidential and private data. Sharing, either way, should not be possible without such an agreement.

210 Power of Regulator to act on requests of overseas regulators, etc

This section should be limited to only formal agreements the Regulator has other international regulators

212 Regulator may request further information, site access, etc

(1)(b) This should only relate to medicines and not medical devices as we should be aiming for 100% reliance on an overseas approval

219 Meaning of making publicly available
(2) The Regulator may also publicise it, or make it available, in any other way the Regulator considers appropriate *with the Sponsor's consent or agreement (to be added)*

Part 7: Enforcement

B29 Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).

232 Regulator may accept undertakings

(6) Why is it only possible for the Regulator to apply for an injunction? If the Sponsor has let the Regulator know someone is acting in contravention to the Bill and that action is causing the Sponsor's organisation financial or reputational harm and the Regulator doesn't take enforcement action, the Sponsor's organisation should be able to seek an injunction to stop the person conducting the action regardless of any other remedies that may be available to the Sponsor's organisation under other New Zealand legislation

Suggest delete 232(6)

The 'and' at the end of 239 (3) (a) should be 'or'
The 'and' at the end of 242 (3) (a) should be 'or'

B30 Please provide any comments on the sections covering penalties, court orders, liability, defences and evidentiary matters for criminal offences (ss 233–248).

235/236 Suspension or cancellation of licence or permit

It would be good for the Court to also be required to take into consideration the potential negative health impacts of such cancellations.

B31 Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).

250 Meaning of infringement fee and infringement fine

(4) Any fines collected pursuant to enforcement activities under the Bill be required to go to offset the costs of the Regulator and not be treated as consolidated revenue

Part 8: Administrative matters

B32 Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts) (ss 256–274).

256 Costs to be recovered

A regulatory scheme must be limited to efficiency costs only. The industry should not be expected to fund the establishment of the Regulator nor the initial operational cost during the transition period.

The Regulator should be accountable for timeframes for product approval and non-performance should incur financial penalties.

The New Zealand Regulator will become a statutory monopoly with payment for its services mandatory. Therefore, The Regulator should not have automatic access to industry funding revenue but seek funds from Parliament through normal budgetary processes using efficiency dividends, benchmarking and market testing third party competition. The protection of health and welfare of the New Zealand population should be a shared responsibility between Government and the industry.

Governance issues should include a requirement to operate through a consultative committee that encompasses stakeholder representation (including the regulated Industry), an independent chairman, an ability to monitor Regulator efficiency, access to adequate information and transparent reporting processes. There needs to independent reviews of industry funding arrangements and independent dispute resolution processes.
A process of measurable performance targets for the provision of the regulatory services, including penalties for non-performance would have to be part of any regulatory scheme to ensure timely assessments are completed.

(Refer "Assessment of Joint Therapeutic Agency Funding Issues" by Bryce Wilkinson 16 December 2004)

267 Consultation

(3) **Delete** this clause
Replace with*: Consultation will constitute not less than 2 calendar months*

268 Minister must review Act

The Medical Technology Industry supports the need to review the Act every 5 years

272 Relationship with Misuse of Drugs Act

The Misuse of Drugs Act should not apply at all to a therapeutic product approved under this Bill where the controlled drug cannot be used as a controlled drug (e.g. the amount included is too small or it's impractical to extract it in sufficient quantities for it to be used as a controlled drug).

Chapter C

C1 Please provide any comments on the approach to regulating changes to approved products (ss 100 and 101).

The Medical Technology Industry questions the need to create a 'new' product approval for changes to devices. There should be more allowance for variations to current approvals. The changed device is not supplied until regulatory approval is obtained (if applicable). Track and trace is achieved through batch/serial records and UDI moving forward.

C4 Please provide any comments on the approach to post-market controls.

The Medical Technology Industry proposes the provision of annual reports for 3 consecutive years from the date of registration for high risk and implantable devices. No annual report on low-medium risk medical devices, unless requested by the Regulator if post-market audit is conducted.

C12 Are there any aspects of the global model for medical devices that you consider to be inappropriate for New Zealand?

The Medical Technology Industry partially supports the intention to adopt the regulatory model initially developed by GHTF and further developed by its successor IMDRF. It is essential that the proposed Therapeutic Products Bill supports the growing momentum for global harmonisation of medical device regulations, and this includes recognition of other international regulators approvals as determined by the New Zealand Regulator.

The Medical Technology Industry supports the requirement for devices to have a globally harmonised unique device identifier (UDI) for traceability and to increase patient safety.

The definition of a medical device (including IVDs) needs to be consistent and reflect the GHTF/IMDRF model to capture the same products that are regulated globally as medical devices

C14 Please provide any comments on the transition arrangements for product approval controls for medical devices.
The intention is to allow a person who lawfully importing or suppling a device or is carrying out a controlled activity before commencement of the new scheme to continue to do so for a 6-month transition period by automatically creating a licence. Within that 6-month period the supplier would need to apply for a product approval.

This requirement for both suppliers and the Regulator would exceed the resources available for most suppliers who would have thousands of devices to apply for licences within the 6-month period and at the same time submit applications for product approvals. It is not indicated how the licence will be "automatically" issued? It may be possible for some form of licence to be generated based on existing WAND entries, however, this will be impossible for IVD medical devices that do not currently appear in WAND.

The intent of this policy does not show any benefit in the short term and logistically would be impossible to achieve. The Medical Technology Industry totally rejects the need to issue licences to continue supply of devices to the New Zealand market at commencement of the Therapeutic Products Bill. Rather, there should be a specific form of medical device application under the new regulatory framework for products legally supplied to the New Zealand market at the date of commencement. This form of application should require the Sponsor to declare that the medical devices covered by the application were legally supplied at the date of commencement.

The Medical Technology Industry needs a **3-year** transition period from the commencement date of the scheme for devices, currently being lawfully supplied in NZ, to apply for a product approval to continue supply with no temporary licence required to be issued by the Regulator.

The Medical Technology Industry suggests as an incentive to encourage early product approval applications, there be a sliding scale of fees charged with no annual fees charged during the transition period of 3 years.

- First year fee free
- Second year 50% fee charged
- Third year 75% fee charged
- All new product approval applications during that transition period of 3 years would attract full fees.

There is the potential for PHARMAC and/or other tender/contract bodies having to be notified of each issued licence (for current devices on market and then again temporary licence before approval) and again once product is approved. The Medical Technology Industry sees no added benefit for the triplicate process and will only cause considerable waste of resources, not only for the industry, but also for those entries that have a requirement to be updated in relation to changing registration details.

The Regulator must demonstrate that the electronic platform being established for product approval applications is proven and reliable before the transition period begins.

C15 Please provide any comments on the transition arrangements for regulating activities involving medical devices.

As above

C16 Please provide any comments on the change in approach to regulating clinical trials.

The Medical Technology Industry is concerned with the requirement for the Regulator to approve clinical trials. The expertise for the proposed approval doesn't reside in the Regulator but in the clinical institutions. Currently, an approval by an Ethics Committee is required to be completed within **45 working days** and that timeframe cannot not be compromised by another process that will create time barriers to the commencement of a clinical trial.

New Zealand has a thriving and growing medical technology research, development and manufacturing sector of approximately $1.4 billion and any compliance or cost imposed by the Regulator must not create barriers to development of this sector.

It also makes no sense at all to require a clinical trial for an approved product within an approved intended purpose (e.g. a post-market pharmacoeconomic study) to be regulated, particularly as the requirement for Ethics Committee approval is necessarily maintained.

C17 Please provide any comments on the transitional arrangements for clinical trials.

S36 –The Principal Investigator should not be the applicant. The organisation that initiates the clinical trial (whether that be the Sponsor, a District Health Board or other research institution) should be the applicant. that is undertaking the clinical trial. It would be difficult to know when the Principal Investigator is going to move and to ensure the Principal Investigator is (and remains) a fit and proper person?