提案された規制経路の重要な特徴	相違点と利点
	信頼を獲得し、それを維持している）EUの第三者認証機関を利用できるようにするインセンティブが提供されることになる。 こうした改善によって、ARTGへの登録に先立って申請監査を受ける機器は、現在、全体の約15%であるのに対し、わずか5%まで減少すると推定される。作業量の減少が見込まれることから、TGAは、現在よりも少ない件数の申請監査を、短い時間で実施できるようになり、その結果、医療技術へのより時宜を得たアクセスが実現すると考えられる。 この改善を実行するには、規制を若干変更しなければならない。
7. TGAが、市販前活動から市販後モニタリングおよびコンプライアンスに、リソースをシフトさせる。	市販前評価の段階で、TGAに求められる取り組みが少なくなることで、余ったリソースを、有害事象報告の処理、製品不具合の早期発見、不遵守に対する規制措置の強化といったTGAの市販後活動に充当することができるようになる。 長い間、MTAAは、TGAの役割はEUにおける監督当局の役割に近いものにすることを提言してきた。しかし、TGAがこうした提案に協力する姿勢を示すことはなく、そのようなことをすれば、現在、医療機器の市販前評価を担当している職員のスキルや専門知識が失われてしまうと主張している。 MTAAは、このようなTGAの主張が、特殊な方法で規制をかける正当な理由にはならないと考えている。というのも、規制

提案された規制経路の重要な特徴	相違点と利点
	当局のリソースは、法律に合致したものでなければならず、その逆はあり得ないからである。 いずれにせよ、MTAA は、市販前評価活動に従事する TGA スタッフのスキルや専門能力について、有害事象が発生した場合に徹底的な調査を行うために、製造業者が保有している文書による証拠をしっかりと理解できることが求められる市販後モニタリングに、そうしたスキルや専門能力を応用することは可能であると提言している。 市販後サーベイランスのためのリソースを追加すれば、時機を逸することなく有害事象調査を実施するという TGA の能力が向上するとともに、機器のスポンサーや製造業者と協力し合うことで、機器に欠陥が見つかった場合には、適切な是正措置を確実に講じることができるようになるだろう。 市販後モニタアリングは、医療機器を安全かつ効果的に使用する上で欠かせないものである。異常は主に製造上の散発的な問題に関連して現れ、それらの異常が、市販前の段階で表面化する、あるいは、容易に検知されることはない。特に、埋め込み型の機器は、人体という複雑な環境の中に長期間留置して使用するため、市販後モニタリングが一層重要となる。 この改善を実行するために、規制の変更の必要はない。

提案された規制経路の重要な特徴	相違点と利点
8. TGA がオーストラリアのスポンサーに『ライセンスを供与』する	現行の規制の下で、医療機器のスポンサー（サプライヤー）は、20 日以内に、製造業者から適合性の証拠を取得できることを保証しなければならない。この要件が意味するのは、スポンサーは、機器の製造業者と能動的な関係を築かなければならないということである。 市販後や記録管理の責任等、規制の下で果たさなければならない責任について、スポンサーが認識していないことはよくある。このことは、TGA の機器有害事象報告（DAEN）のデータベース上に報告された内容を見れば明らかである。スポンサーと製造業者との関係は、有害事象やクレームを、設計・開発プロセスに確実にフィードバックする上で不可欠なものである。 提案されたモデルでは、TGA は、スポンサーに『ライセンスを供与』して、オーストラリアで医療機器を供給できるようにする。スポンサーにライセンスを供与するには、製造業者との間に能動的な関係が構築されていること、また、適切なシステムやリソースの配備によって現行の規制要件が満たされていること（有害事象を報告することができる、認知された業界実務規範を遵守している等）を確認しなければならない。この改善を実行するには、規制の改正が必要である。
9. ARTG における機器の可視性を改善する	MTAA は、製品の ARTG への登録方法を変更して、オーストラリアで現在供給されている、または、かつて供給されていた医療機器を容易に特定できるようにするべきであると提言してきた。

提案された規制経路の重要な特徴	相違点と利点
	この改善を実行するには、規制の改正が必要になる可能性がある。

提案により改善されるシステムの段階的実施

MTAAは、提案された規制システムの改善策の多くに、法改正や国際協力、TGA内部のプロセスおよびITシステムの変更が必要になることを認めている。そのため、すべての変更を同時に実施しようとするのではなく、2～3年という期間をかけて、段階的にこれらの改善策を展開していくことを提案している。主な変更は以下の段階を踏んで実施することが提案されている。

段階	説明
1. オーストラリアの製造業者、および、一部のクラスⅢの機器に対して、ARTGへの登録に先立って、TGAの適合性評価認証を取得することを義務付ける規制4.1を廃止する。	この変更はただちに実施可能であるが、変更後も、製造業者が、EUの第三者認証機関からCE認証を取得することを希望しなければ（例えば、オーストラリアの小規模な製造業者が、EU内での製品の供給に興味を示していない場合等）、これまで同様、適合性評価認証の取得のために、選択肢の1つとして、TGAを利用することができる。 TGAの適合性評価認証を保有する製造業者は、これに替えて他のCE認証を選択することができるが、そのためには、現在、規制5.3によって義務付けられているように、ARTGへの登録に先立って、クラスⅢまたはAIMD機器を新たに申請することにより、TGAによる申請監査を受けなければならない。 MTAAは、この変更の実施にあたり信頼醸成活動の着手を待つ必要はないと考えている。というのも、これまでTGAによる適合性評価の対象となってきたリスクの高い機器（薬剤または動物由来の材料を含有するもの等）については、今後も、ARTGへの登録の前に実施される市販前申請監査の際に、TGAによるレビューが行われるからである。

2. TGAが、EUの第三者認証機関および／またはEUの監督当局と信頼醸成活動を行うことにより、『推奨』第三者認証機関リストを作成する。	以下を通じて、これを実現する。 • すでに信頼醸成のための条項が含まれているオーストラリアとEU間の相互承認協定（MRA） および、 • TGAが現在行っている、IMDRF医療機器単一監査プログラム（MDSAP）への関与 これが実現すれば、製造業者が、『推奨』されるEUの第三者認証機関の1つによって発行されたCE認証書を利用する場合、TGAは、ARTGへの登録の前に行う、申請監査の対象となる機器の選択から、該当する機器を除外できるようになると考えられる。そのためには、規制5.3を若干変更しなければならない。
3. TGAが、適合性評価機関（CAB）として機能することをやめ、第三者CABを指定して、オーストラリアCA認証書を発行する。	この局面では、構想を練り、実現するための時間がおそらく追加で2～3年必要になるだろう。 このような枠組みを構築する段階で、十分な数のCABが指定され、オーストラリアの製造業者が、自社の認証を新しいCABの1つに移行するための準備が整うまで、TGAには、独自のCA認証サービスを続けることが求められる。

提案により改善される規制システムのSWOT分析

強み	弱み
• 適合性評価機関の能力への信頼が高まる。 • スポンサーが規制義務を満たしているという信頼が高まる。	• 国民の間に、また、政治的観点から、規制当局の統制力が低下したとの認識が生まれる。 • 規制当局および業界のスタッフの再

• 患者の安全性を低下させることなく、不要な手続きを減らすことができる。 • 医療技術へのより早いアクセスが可能になる。 • 指定制度は、ANZTPA の下でのニュージーランドのニーズに見合ったものになると考えられる。ニュージーランドの業界は、TGA の市販前承認プロセスについて、懸念を表明してきた。	訓練が必要となる。
機会 • ANZTPA によるベストプラクティスな規制。 • 市販後活動のためのリソースを増大させることで、規制当局の対応が迅速化し、結果的に、患者の安全性が向上する。 • 市販後活動のためのリソースを増大させることで、医療機器の使用に関する諸問題について、他の医療部門に報告するという規制当局の取り組みをサポートし、機器の上手な使い方を推奨することができるようになる。 • 地域の適合性評価機関に専門知識が求められることで、雇用が創出される。 • 地域の製造業者が、他の管轄区域に対して製品を評価する適合性評価機関にアクセスすることで、他国の要件と製品の照合ができるようになる。 • スポンサーへのライセンス供与。	脅威 • 消費者の懸念。 • 政治的環境。 • 法律（ANZTPA）の大幅な改正。

リスク緩和

リスク	緩和措置
国民の間に、また、政治的観点から、規制当局の統制力が低下したとの認識が生まれる。	システムについて、公的および政治的教育を行うことで、適合性評価機関の指定やスポンサーへのライセンス供与、プロセスの

	透明性に関する周知を図る。 規制当局による市販後活動、および、医療制度へのアドバイスを強化することで、患者を保護するために、最も効率的な措置が講じられているという信頼を高める。
規制当局および業界のスタッフの再訓練が必要となる。	TGA と業界のどちらのスタッフも、規制要件に精通していることから、新たな役割または役割の拡大に応じたスタッフの再訓練が、深刻な問題になることはない。
消費者の懸念と政治的環境。	適合性評価機関の指定および責任を担うサプライヤーへのライセンス供与について、 透明性を確立する。
法律の大幅な改正。	共同規制機関である ANZTPA に対して、規制の改正が必要になることにより、的確に対応するための機会が生まれる。

7. 結論

MTAA は、現行の医療機器規制システムにおける形式主義に関して、多くの具体的な事例を提示することができるのだが、そうした事例の多くは、これまでに協議や規制会議の場で、TGA との話し合いの議題に上げられてきたものである。

市販前評価の変更に関して、TGA が最近提出した規制影響報告書（RIS）に対する MTAA の反応が示しているように、リスクの高い機器への市販前要件の追加を提案しても、PIP 社製乳房インプラントや ASR 股関節置換の問題に相当するような、プロファイルの高い機器の不具合を防ぐことはできないだろう。市販後のフィードバックを迅速に分析し、傾向を把握し、対応することによって、最終的に、患者の安全性を向上させることができるかどうかは、TGA の能力次第なのである。

適合性評価機関の指定、および、現在行われているモニタリングは、医療機器の徹底的な評価が、相応の資格と専門知識を有する人たちによって行われているという信頼を揺るぎないものにするだろう。

スポンサーへのライセンス供与は、スポンサーが医療機器をオーストラリア市場に供給

する能力を有し、製品のライフサイクル全般にわたって、現行の規制義務を理解しているという確信を、規制当局に与えるだろう。

MTAAは、本白書で要点を述べた変更の提案を通じて、TGAの効率とバリュー・フォー・マネーが向上し、結果的には、オーストラリアの企業に大幅なコスト削減をもたらすとともに、最も重要なこととして、オーストラリアの患者の健康転帰の改善につなげることができると確信している。

資料2-2

White Paper:

Improvements to the Australian Regulatory System for Medical Devices

23 May 2014

mtaa.org.au Medical technology for a healthier Australia

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1. Executive summary

This paper outlines some of the regulatory challenges experienced by Australian businesses involved in the supply of medical technology, and proposes an improved system that significantly reduces the regulatory burdens on industry, without compromising the quality or safety of medical devices supplied in Australia.

The current Australian regulatory system involves significant red tape for businesses, particularly in relation to the time and cost of bringing medical devices to market. This may contribute to companies deciding not to bring the latest medical technology into Australia, and thereby depriving Australian patients access to the clinical benefits of the most modern technology available in other developed economies.

A number of opportunities for improvement exist, including the Therapeutic Goods Administration (TGA):

- taking on the role of a designating authority of third-party conformity assessment bodies
- ceasing to conduct duplicative pre-market assessments already conducted in other similar regulatory jurisdictions
- improving internal systems to remove unnecessary steps in the pre-market application process
- increasing resources devoted to post-market monitoring and compliance activities
- licensing suppliers of medical devices requiring them to adhere to industry codes of practice.

The expected results of implementing these improvements would include:

- more timely access to the latest medical technology for Australian patients
- a decrease in pre-market regulatory costs for Australian businesses
- more predictable and timely regulatory processes for Australian businesses
- maintaining an equivalent level of quality, safety and performance to that of medical devices already on the market
- earlier detection of device failures and increased ability of TGA to react quickly, thereby reducing the number of Australians adversely affected by potentially unsafe devices
- greater confidence in the supplier's ability to support devices throughout the product lifecycle.

The suggested improvements would remove red tape and duplication in the current regulatory system while improving patient safety, and allow TGA to operate more efficiently and effectively.

2. About the Medical Technology Association of Australia

The Medical Technology Association of Australia (MTAA) represents the manufacturers, exporters and suppliers of medical technology products in Australia. MTAA represents companies which account for the majority of products included in the Australian Register of Therapeutic Goods (ARTG), and approximately 75% of implantable medical devices listed on the Prostheses List used in the Australian marketplace. MTAA member companies cover the full spectrum of the industry in Australia; from subsidiaries of major multinational medical technology companies, to independent distributors and small-to-medium sized Australian innovator companies.

3. Aim of the paper

This paper aims to:

1. Describe the current Australian regulatory system for medical devices and how it compares to that of other developed economies.

2. Identify elements of the current system that:
   - result in unnecessary red tape for Australian businesses, and
   - delay or prevent access to modern medical technology for Australian patients.

3. Propose options for improving the regulatory system to:
   - reduce or eliminate red tape for Australian businesses,
   - increase Australian patients access to the benefits of the latest medical technology, and
   - strengthen the post-market monitoring and compliance regime,

   without compromising the quality, safety or performance of medical devices supplied in Australia.

4. The current Australian regulatory system for medical devices

Australia was a founding member of the Global Harmonization Taskforce (GHTF), which was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. At its inception GHTF was comprised of representatives from five founding members (Australia, Canada, European Union, Japan and United States), each of which actively regulated medical devices using their own unique regulatory framework.

The purpose of GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this was accomplished was via the publication and dissemination of harmonised guidance documents on basic regulatory practices, which could be adopted/implemented by member national regulatory authorities.

In late 2011 GHTF was replaced by the International Medical Devices Regulators Forum (IMDRF), which Australia (TGA) was also a founding member. IMDRF aims to accelerate the international medical device regulatory harmonisation and convergence started by GHTF.

The GHTF model was fundamentally based on the European regulatory system adopted in the early 1990s, and included the following key elements:

- Pre-market evaluation:
  - Definitions of key terms, including 'medical device' and 'manufacturer'
  - Rules-based risk classification system
  - Conformity assessment procedures to be followed by manufacturers, including the requirement to implement a Quality Management System (QMS) and post-market surveillance system
  - Standards and Essential Principles to demonstrate the safety & performance of medical devices, including requirements for labelling
- Post-market surveillance & vigilance
- QMS & auditing
- Clinical safety & performance

The Australian regulatory system (adopted in 2002) is based on this GHTF regulatory model and is therefore also closely aligned with the European Union (EU) regulatory system for medical devices. Adoption of this system in Australia provided more opportunities in the global market for Australian manufacturers.

The requirement for medical devices to meet the Essential Principles for safety and performance was legislated in 2002 in the *Therapeutic Goods (Medical Devices) Regulations 2002*. The regulations are administered by the Therapeutic Goods Administration (TGA). These regulations prescribe a risk-based system for the assessment of conformity to the Essential Principles. The greater the risk carried by the product (in terms of how invasive within the human body it is, the duration of use and the risk it poses to people), the more stringent the conformity assessment procedure that needs to be applied by the manufacturer.

The regulatory system effectively requires manufacturers of medical devices to apply internationally harmonised standards to the design and manufacture of their product to demonstrate compliance with the Essential Principles. This includes compliance with the international QMS standard (ISO13485), which requires manufacturers of medical devices to establish and maintain the high quality of design, manufacturing and post-market monitoring necessary for medical technology, is a pre-requisite for all but the lowest risk (Class I) medical devices.

Assessment and certification of a manufacturer's QMS occurs before manufacturers can supply their products. Continued adherence to the QMS requirements is also assessed through regular surveillance inspections. This continuous monitoring and surveillance ensures that medical devices are manufactured to their specification and continue to perform as intended.

Devices manufactured by Australian manufacturers, and a sub-set of high risk devices (such as those containing medicines or materials of animal origin), must obtain conformity assessment certification from the TGA prior to supply in Australia. For all other kinds of devices (including high risk implantable devices such as pacemakers and artificial hearts) the TGA will accept European CE certification issued by an EU Notified Body (NB).

Once conformity assessment certification has been obtained, the manufacturer signs a 'Declaration of Conformity' declaring that they have applied the relevant conformity assessment procedures, and that the devices comply with the Australian Essential Principles for safety and performance.

The Australian 'sponsor' is the entity responsible for the importation and supply of the device in Australia, and they can use the certification as evidence to enter the device in the Australian Register of Therapeutic Goods (ARTG). It is a requirement for the sponsor to include the device in the ARTG before it can be supplied in Australia (with some exceptions, such as custom-made devices).

For higher risk devices (Class III and some Class IIb) that have undergone conformity assessment by an EU Notified Body, TGA will conduct a further 'application audit' of the documentation supporting the conformity assessment certification before including the device in the ARTG.

Figure 1 below shows the current main supply pathways for medical devices in Australia. This does not show all the possible pathways for supply, as there are many exceptions and options in the legislation available to sponsors, such as Clinical Trial and Special Access schemes, which are not represented.

The TGA processing times and proportion (%) of devices subject to each time frame are approximations only. Due to the lack of equivalent published data from TGA, these figures have been estimated based on a combination of previously reported figures from TGA, the proportion of different device classifications included in the ARTG, and indicative feedback from MTAA members.

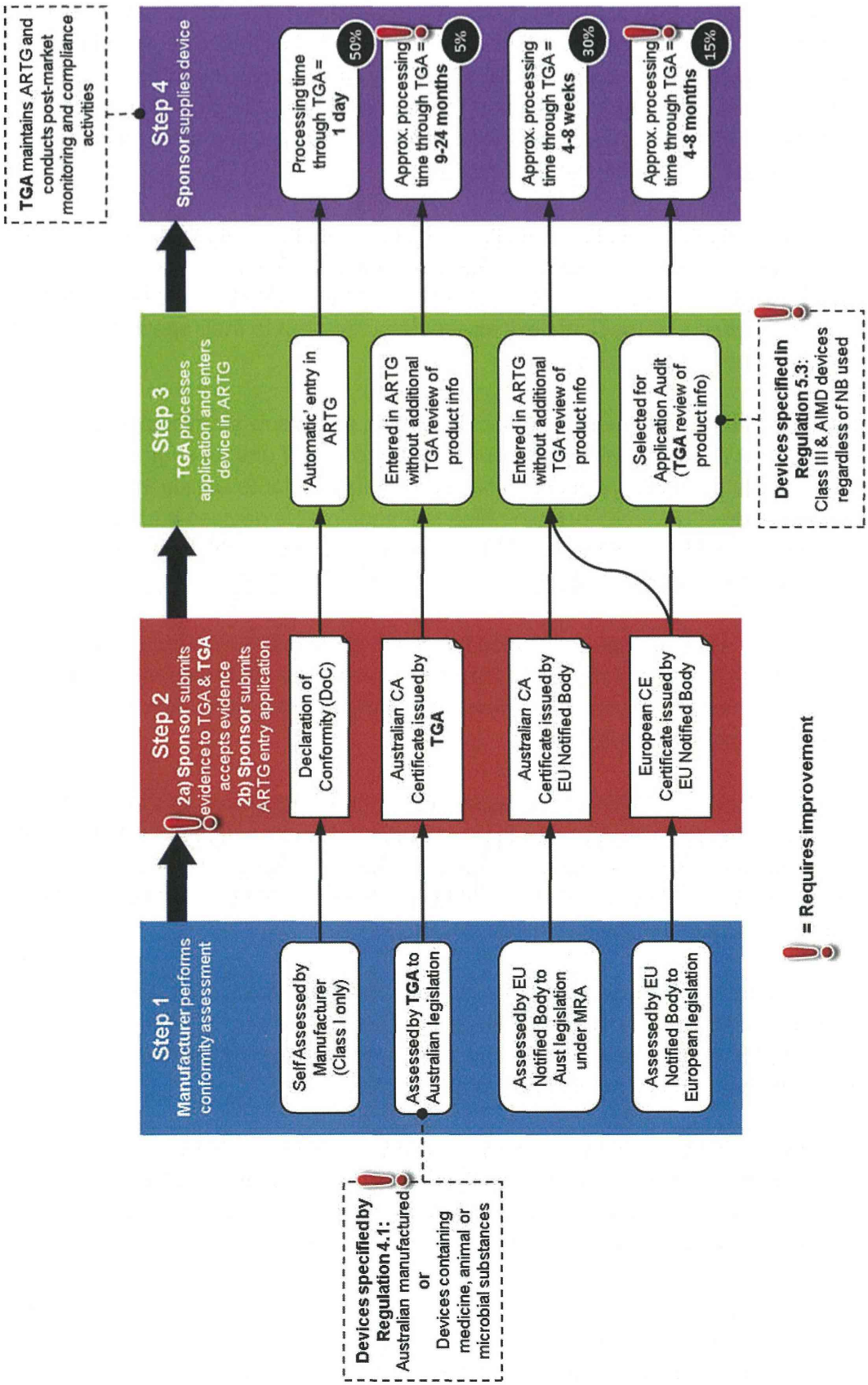

Figure 1 - Current Regulatory Supply Pathway for Medical Devices in Australia

Link between the Australian and European regulatory systems

The Australian and European systems are similar in that a manufacturer must apply a conformity assessment procedure (including an audited QMS) to demonstrate that a device meets the requirement of the 'Essential Principles' of safety and performance. In the EU these are known as the 'Essential Requirements'. Risk-based classification of medical devices in Australia and EU are generally the same, as are the different conformity assessment procedures applicable to each classification of device.

The differences in regulations include specific requirements of the two regions local laws; other differences are minor enough that European conformity assessment certification can be used by Australian sponsors to include devices in the ARTG.

Most medical device manufacturers will gain EU certification to commercialise the device in Europe prior to including the device in the ARTG and supplying the product in Australia. This is in large part due to:

- the relatively large market size of Europe (approximately 30% of the global market) compared to Australia (around 2% of the global market)
- the time to gain CE certification from an EU Notified Body (approximately 3-4 months) compared to the time it takes to gain TGA conformity assessment certification (usually between 9-24 months)
- the cost of obtaining EU CE certification compared to the cost of obtaining TGA conformity assessment certification.

EU Notified Bodies and Competent Authorities

In the EU conformity assessment of medical devices is undertaken by Notified Bodies (NB). These bodies are impartial, independent third-party commercial organisations specifically designated to monitor and review conformity assessment procedures applied by medical device manufacturers. Each member state of the EU has a Competent Authority (e.g. in the United Kingdom the Competent Authority is the Medicines and Healthcare Products Regulatory Agency (MHRA)), which is responsible for implementing the European laws ('Directives') nationally, and designating Notified Bodies (e.g. in the UK BSI and SGS are Notified Bodies) within their respective nation.

The member state Competent Authority will assess a resident Notified Body's organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in activities related to medical device assessments.

If a Notified Body meets the criteria, the Competent Authority recommends that it is listed on the *Official Journal of the European Commission* (OJ). Notification stipulates the specific directive areas in which the Notified Body has been approved (e.g. medical devices or consumer electronics). It is not uncommon for a notification to also list specific product groups, which the Notified Body is approved to assess (e.g. active medical devices or implantable medical devices). The designating Competent

Authority is responsible for periodically assessing the resident Notified Bodies to ensure continued compliance with the standards for assessment.

Competent Authorities are also responsible for post-market monitoring of medical devices. Under the EU Directives a manufacturer of medical devices supplied in the EU must report adverse events involving medical devices to the Competent Authority of the nation where the event occurred. It is the Competent Authority's responsibility to investigate, monitor and trend adverse events so they can initiate recalls or provide advice to the health system of other Competent Authorities and regulators around the world.

TGA operates in a similar fashion, in that it performs the function of a Notified Body for pre-market device and manufacturer assessments, but also has the post-market monitoring and vigilance responsibilities of a Competent Authority.

5. Issues with the current Australian regulatory system

Although closely aligned with the regulatory requirements in Europe, there remain a number of aspects of the current Australian regulatory system, which result in Australian medical technology companies experiencing unnecessary and burdensome costs to their business, and ultimately affect the ability of Australian patients to access the latest medical technology.

These issues can be broadly categorised as follows:

- unnecessary duplication of effort by TGA
- high TGA costs and lengthy and unpredictable processing times
- unique Australian-only requirements (such as the ARTG).

Duplication of effort

The TGA process for including medical devices in the ARTG has often been criticised as being repetitive of the assessment undertaken by EU Notified Bodies. The necessity in the regulations for TGA to conduct mandatory application audits of documentation supporting some higher risk devices is repetitive of the assessment undertaken to gain European CE mark certification. The audit of documentation supporting higher classification devices is intended to give TGA confidence that the work undertaken by European Notified Body is sufficient for the EU Certification to be accepted as evidence to support compliance with Australian regulations.

However, this TGA review process is conducted on a product-by-product basis, even though the same CE certification may be used by the same manufacturer for their entire range of devices. One could argue that if TGA was willing to accept the certification issued by a particular Notified Body for a particular device and manufacturer, there should be no need to conduct another review of similar devices from the same manufacturer, as the certification issued by that Notified Body has already been found to be acceptable.

TGA has recently advocated that an increase in pre-market assessment is required to gain confidence in the EU Notified Bodies' ability to undertake conformity assessments. But there has been no proposal to reduce the level of pre-market assessment conducted by TGA once that confidence building activity has been undertaken.

For devices required to obtain TGA conformity assessment certification, such as those made by Australian manufacturers and those containing medicines or materials of animal origin, there is also a duplication of effort by TGA in addition to the assessment already conducted by the EU Notified Body during the CE marking process.

Once again, this would appear to be an unnecessary duplication of effort as the quality, safety and performance requirements are effectively identical to those in Europe.

There has also been no review of the TGA's ability to conduct conformity assessments by an independent third-party (such as required of a Notified Body by their EU Competent Authority). Therefore there is no evidence to suggest that an assessment conducted by TGA is any more comprehensive or reliable than that conducted by any EU Notified Body.

MTAA suggests that in conducting its own conformity assessment review the TGA does not necessarily add any additional value to the review already performed by EU Notified Bodies. Therefore TGA is no more likely to identify actual problems with the quality, safety or performance of medical devices before being supplied in Australia.

One example of this is the silicone breast implants produced by French manufacturer Poly Implant Prosthese (PIP). The issues surrounding the failure of the PIP breast implants are well known and were the subject of a Senate Community Affairs Committee inquiry in 2012. The Department of Health's own submission to the inquiry indicated that:

> *In April 2003, Medical Vision Australia submitted an application to the TGA for a Conformity Assessment Certificate to be issued to PIP for high and standard profile silicone gel pre-filled breast implants for use in breast augmentation and reconstruction.*
>
> *The TGA conformity assessment review was conducted over an 18 month period (May 2003 to October 2004) and included the following elements:*
> 1. *Review of the manufacturer's QMS, which included an onsite audit of the manufacturing facility in France.*
> 2. *An examination of the design of the PIP implants, including detailed assessments of the following aspects:*
>   - *a microbiological review relating to packaging, shelf life and sterilisation validation activities;*
>   - *a biocompatibility and biological safety review, including a review of the cytotoxicity, genotoxicity and reproductive toxicity of the various materials used in the implants;*
>   - *a review of materials engineering (mechanical and chemical performance) and manufacturing processes, including physical strength of the shell, and detailed information on the description of polymerisation, curing and catalytic conditions of every step of manufacture of the shells, patches, glue and filling gel for the products;*
>   - *an assessment of clinical evidence.*
>
> *On 18 October 2004 the TGA issued a Conformity Assessment Certificate to PIP for the manufacture of nine models of silicone gel-filled implants. In accordance with standard TGA (and international) practice, the TGA Conformity Assessment Certificate was valid for five years so would expire on 18 October 2009.*

This clearly demonstrates that even when TGA conducts its own rigorous conformity assessment review of high risk devices and their manufacturers, this does not prevent potentially unsafe product from being supplied in Australia, and does not result in a different outcome compared to the equivalent assessment conducted by a suitably qualified and experienced EU Notified Body.

TGA costs and processing times

The TGA's costs for conducting pre-market assessments of medical devices and their manufacturers are considered to be some of the highest regulatory costs in the world. This is exaggerated further when taking into account the relatively small market size of Australia (less than 2% globally).

Similarly, the TGA's processing times for pre-market assessments are often considerably longer than those in other comparable regulatory jurisdictions such as Europe and Canada.

Unlike other regulators in developed countries under the current regulatory system the TGA's activities are fully cost recovered from industry. Although conformity assessments conducted by TGA are relatively expensive compared to an EU Notified Body, the additional cost does not translate to greater efficiencies in the TGA or better outcomes for patients. A conformity assessment conducted by TGA can take two years or more, compared to a standard 90-day assessment, or 45-day expedited assessment, by an EU Notified Body.

It is clear to industry that yearly increases in TGA fees and charges have not been invested in process improvements that are required to make the regulatory system more predictable and efficient.

Most conformity assessments conducted by TGA are undertaken for devices containing medicinal substances or materials of animal origin. Once TGA certification has been gained, any changes to those devices must also be assessed by TGA. These submissions for assessment of changes can take over 18 months to review. During this time, the overseas manufacturer, which has had the change assessed and approved by FDA (notification) and the EU Notified body (one month), may have to stock pile the superceded version of the device for supply in Australia until TGA has completed its review. Due to the unpredictability of TGA review time frames the stored products may expire resulting in users having to switch to using a different device, which poses usage risks, until the TGA review process is complete.

TGA's timelines for conducting conformity assessments are highly unpredictable, with some companies reporting assessments taking over two years to complete, compared to a standard 90-day assessment by a European Notified Body. In the case of an Australian manufacturer of high risk devices this has resulted in its products being launched in the EU prior to Australia and substantial delays in gaining regulatory approval in other markets that require 'country of origin' approval (principally in the Asia-Pacific region).

Unlike many pharmaceuticals the product life-cycle for medical devices is relatively short. Many medical devices typically have a commercial life of around 18-24 months before an improved product becomes available and replaces it on the market. The pace at which this continual development and improvement process occurs means that some devices are never supplied in Australia because the time taken for the TGA assessment process exceeds the life of the product itself.