TGA Invitation to Comment

RE: Recommendation eight, regulatory reform proposal three and four of the Reforms to Medical Devices Regulatory Framework.

I would like to specifically comment on the proposal 3(i) and 3(ii) as follows.

I believe there is a **smart solution** to achieve the **desired outcomes of the T.G.A**. that will have a **minimal impact** on industry whilst providing the T.G.A. and the end consumer far greater access to detailed device information.

Let me begin by summarising my understanding of the desired needs and outcomes that drive these specific proposals.

(i) The TGA is currently unable to identify the relationship between an ARTG entry and the individual medical device's associated with the ARTG entry.

(ii) Consumers and healthcare professionals wish to know that a device has a valid ARTG entry and potentially access detailed information about a device.

(iii) Regulation 10.2 is required by the TGA to enable the device to be identified and connected to an ARTG entry on the register.

Note that this is my *interpretation*, which I assume, but do not presume to be correct.

The current legislation surrounding labelling and identification of medical devices, whilst well intentioned, is fundamentally flawed and adds significant impost to *those within the industry who are actually abiding by the rules*, whilst being ineffective against those that are not. To say this another way, the significant overheads and costs to do the right thing are born by those sponsors doing the right thing, and the very purpose behind the reg 10.2 does not indeed actually facilitate the desired outcome of the TGA intended by 10.2.

Let's look at two principal facts first.

1. Just because I supply an ARTG number on the device, *DOES NOT* mean that the device has a valid ARTG entry. If I have already chosen to break the law and import/sell/distribute devices without the appropriate approvals, it is simple to take an existing, similar ARTG number and apply it to my product. Unless you check the ARTG entry against an identifiable ARTG register, simply applying a number/label will not facilitate point (ii).

2. For similar reasoning to point 1 above, including a sponsors name and a manufacturer name on the device also does not necessarily mean that the device has a valid, connected ARTG entry.

Let's also consider the advent of the National Product Catalogue, which is a database operated outside of the T.G.A. framework, although it's now becoming a

requirement for all government and many private contracts. This database contains many (but not all) medical devices, with their specific ARTG entries, packaging formats, GTINS and a great deal of other pertinent information. A point to note, is that this database is (a) now the foundation used by industry for medicine and device data sharing and (b) entries in the NPC do not guarantee a valid Aust R, Aust L or ARTG entry. Essentially we have the regulatory body with a system built for regulatory (not commercial use) and a commercial system not connected to the regulatory body.

The NPC is founded upon the international standard of GTIN's, used by companies all over the world to easily identify products, including product variants, and ensure product dispensing errors do not occur.

It must also be considered that the Australian Healthcare market is but a drop in the ocean when compared to world wide pharmaceutical and medical device consumption. Very little of our consumed medical devices are indeed manufactured either (a) in Australia or (b) specifically for the Australian market. Attempting to force the application of country specific labelling to product often manufactured for world markets, whilst ignoring currently available international standard product identification systems is not helpful to the industry, and as argued above, I believe does not actually created the desired outcome by the T.G.A. in points i-iii above.

Proposal 1

I would propose that regulation 10.2 be amended so that medical devices must include an identifiable GTIN (scannable or not), and remove the need to identify the sponsor and manufacturer.

Reason :

(a) There is significant cost to apply country specific labelling to facilitate localization of international products.

(b) Forcing the inclusion of both Manufacturer and Sponsor severely disadvantages smaller sponsors in the market as it readily identifies your buying source.

(c) It's impractical to label may devices on the individual device or it's individual packaging, which leads often to this information being provided on packaging, labelling or other documentation that is functionally separated from the device prior to consumption – negating the desired outcome of 10.2 (and points i-iii) – therefore cost and overhead is added without obtaining the desired outcome.

(d) GTIN's are the only world accepted, world recognised, common product identification format available with any market penetration today. Multinational manufacturers can apply a GTIN for ANY market and it identifies SPECIFICALLY a device, down to it's consumed package format.

Cost Benefit:

Consider the following

- the cost of a label for 500-1000 units is approximately 10 cents USD (often higher). The cost of a label for between 1000-10000 pieces is approximately 3 cents[1].
- The cost to apply a label is often 5-10 cents[2] offshore in China & India, or as much as $1.00-$3.00 per unit in Europe, USA, Australia etc.
- This cost is passed to the manufacturer, who in tern applies a margin (most multinationals are measured on % gross profit, so if you add cost, the sell price must change to maintain the % GP).
- The manufacturer often then sells the goods to a distributor, who adds a margin to the now higher price. Again, it's a percentage.
- This then get's passed on to the a healthcare provider, who adds a margin.
- This cost is then picked up by one of three parties
  (a) the government through Medicare
  (b) private health insurance
  (c) the consumer
- Putting it simply, $1 at the bottom equals around $4-$5 at the top. The general rule of thumb is somewhere between a 4x-5x increase by the time the item is consumed.

Multiply this out by the number of medical devices in Australia and you get a scary number. Then consider that the government is funding a good chunk of it. Then consider that it's not delivering the desired outcome.

Proposal 2

Either update the current EBS system to replace the NPC and provide the functionality of the NPC, OR partner with the GS1. If industry is already funding the cost of the NPC, don't do it twice! Functionally the system could work as follows.

1. An ARTG entry is applied for and approval granted by the TGA through EBS.
2. Once approved the entry is published to the sponsor side of the EBS system and the details are electronically pushed to the NPC.

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[1] It is possible to reduce this further by increasing the number of labels, but the counterpoint is this, for products that are manufactured in the 10,000+ quantities, these are typically produced in the 1,000,000+ quantities for international markets and Australia consumes the 10,000+ units from this large quantity.

[2] This is assuming a label is applied rather than modifying the entire packaging and reprinting so suit.

3. Sponsors can then enter all device and variants, related directly to the approved ARTG entry, into the NPC using the now well-developed systems and interfaces for product entry.
4. If the status of an ARTG entry changes, this data is **automatically** passed from the T.G.A. to the NPC, immediately informing the market electronically.

There is no point to having two independent systems for market access. With very little cost (the supplier side is already developed with most public hospitals and health care facilities already interfacing electronically with the NPC) a simple portal for health professionals and consumers could be provided with the following benefits.

1. Excluding the very limited costs to being on the NPC, this system would not apply any additional cost overheads to the sponsor as they have to enter product into the NPC to sell to public healthcare already.

2. Every specific item would be associated to an ARTG entry. The TGA could view an entry and obtain a list of every item associated with that entry, including potentially images and labels.

3. It immediately solves the problem of labelling, allowing all sponsors to use internationally recognised and accepted labels and numbers for product identification.

4. It completely resolves point i. without any additional cost to the TGA or industry.

5. It resolves point ii. Without any additional cost to the TGA or industry, even to the point of providing far better information, including complete label identification to everybody (hospital, healthcare practitioner or consumer).

6. It resolves point iii. In a far more efficient way than the current system AND enforces it. (i.e. if the TGA cancel / amend an entry, this is immediately pushed to the market.

7. End Users can immediately validate that the device in their hand is the device on the registry, by matching the labelling & packaging. Essentially – **no cheating!** Sponsors upload the product image as associated with the GTIN into the NPC, functionality that is already available and in existence and in some cases required by end users now (I'm happy to give you a GTIN primer if you are not familiar with the GTIN rules). End users can literally match the image on record with the product. If it's not the same, it's **not the registered product**! It's a fairly extensive procedure to counterfeit packaging and for higher risk products the security mechanisms afforded by GTIN and RFID technology provide significant protection against IP theft. Unless you give the end user a way of visually matching the registered product with the actual product, the system is flawed because it relies on assumption (even with an ARTG number on the label) that the ARTG entry = the product in your hand.

8. Consider the benefit to a healthcare organisation of being immediately informed of a device warning or failure, and being able to immediately identify stock quantities of affected batches. If scanning was implemented, patient

management systems could immediately intervene and prevent further use of affected items.

Conclusion.

If indeed the TGA operates on a cost recovery model, adopting the above proposals would deliver all of the desired outcomes, significantly reduce the regulatory burden on industry, provide far superior information to the healthcare sector, meet all the target outcomes the T.G.A. is looking for and reduce duplicity (it's pointless duplicating EBS and NPC, join the dots and everybody is going to be far better off).

My background is in fast moving packaged goods and I have been involved in the identification of product for years now, but in a different industry. Perhaps the T.G.A. can learn from the experience of the grocery markets worldwide, where product is easily identifiable (right down to the apple, who made it, and if you are really really cleaver – you can tell who handled it all the way through the supply chain. Consider the fact that this system (particularly in pharmaceuticals) has the potential to almost **99.99% prevent human dispensing errors** (we called them picking errors in warehouses years ago), provides item traceability from source to consumption (I think the T.G.A. would like that), is a tried and tested, world compatible system(many of Australia's leading sponsors have already adopted GTIN's), facilitates international distribution of medical devices because it *reduces specific localization*, addresses all of my assumed required outcomes needed by the T.G.A, and costs next to virtually nothing to implement, surely it must be considered as a significantly better alternative.

Best regards,
Chris Pope.
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