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Compulsory registration with GS1 Recallnet Healthcare for sponsors wishing to participate in state tenders: The case for reducing red tape

Executive summary

This paper has been prepared by the Medical Technology Association of Australia (MTAA) in response to feedback from its members regarding GS1 Recallnet Healthcare, hereafter referred to as Recallnet, a service intended to assist with recalls of therapeutic goods in Australia. Recallnet involves a software application requiring data entry and maintenance by sponsors of therapeutic goods, for which sponsors are charged an annual fee. Recallnet went live on 1 April 2014. In Victoria, registration with Recallnet has effectively become compulsory for suppliers wishing to participate in tenders for public sector contracts.

Medical devices are highly regulated in Australia and sponsors must comply with the Therapeutic Goods Administration (TGA) uniform recall procedure for therapeutic goods (URPTG). TGA's position on Recallnet, which is posted on its website, states clearly that "it is not a requirement for sponsors of therapeutic goods in Australia to join GS1 Recallnet Healthcare to undertake recall actions".

Recallnet's current limitations are such that it does not facilitate sponsors meeting all of their relevant regulatory obligations for medical device recalls. As a result, sponsors must maintain two systems in parallel for product recalls: one that allows compliance with all regulatory requirements and Recallnet (which is effectively required to compete for public sector business in Victoria).

For this reason, compulsory registration with Recallnet represents an additional administrative and financial burden on sponsors.

The ability to manage recalls efficiently is critical to ensuring patient safety. Sponsors of therapeutic goods are concerned that if the other States and Territories mandate registration with Recallnet too, this will result in significant red tape that will impede sponsors' ability to manage recalls and safety notifications in the most efficient way.

Accordingly, MTAA's view is that registration with Recallnet should be voluntary.

GS1 Recallnet Healthcare – background information

Recallnet's website states that: "GS1 Recallnet Healthcare is a service designed to assist with the issue of product recalls and non recalls in the Australian healthcare sector. With GS1 Recallnet Healthcare, healthcare manufacturers, distributors, wholesalers, hospitals and state based health authorities can now initiate, receive and exchange information

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relating to healthcare recalls and withdrawals online and at any time, thus enabling the fast and efficient removal of unsafe or unsuitable products from the supply chain, retailers, hospitals and the wider marketplace." (1)

GS1 Australia collects annual user fees for the Recallnet service on a cost-recovery basis. The fees are calculated based on a company's gross annual turnover. The schedule of fees effective 1 July 2015 is shown in Figure 1. (2)

Recallnet & Recallnet Healthcare Service Fees

Gross Annual Company Turnover		Recallnet Fees*	
From	To	Member Rate**	Full Rate
NIL	<$1M	$120.00	$156.00
$1M	$5M	$258.00	$330.00
$5M	$10M	$390.00	$492.00
$10M	$50M	$522.00	$648.00
$50M	$100M	$1,044.00	$1,296.00
$100M	$500M	$1,656.00	$2,052.00
$500M	$1B	$2,022.00	$2,520.00
$1B		$2,448.00	$3,060.00

** Fees shown are exclusive of GST*

*** Available only for GS1 Australia members.*

Figure 1: Recallnet fees as of 1 July 2015

In Victoria, registration with Recallnet was effectively made compulsory for companies who wish to participate in tenders in the public healthcare sector by Healthcare Purchasing Victoria (HPV). HPV was established in 2001 "to improve the collective purchasing power of Victorian public health services and hospitals" and "facilitate large scale tenders and manage common-use contracts on behalf of the state". (3)

Companies wishing to supply medical devices to the public healthcare sector in Victoria must either be registered with Recallnet at the time of the tender or register within a "specified period of time" if they are the successful bidder. In a FAQ document posted on its website, HPV states: (4)

> **Do I need to be using Recallnet to participate in a HPV tender?**
>
> No. The HPV tender requirement is for successful suppliers to be using Recallnet within a specified period of time from the commencement of the contract.

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Asked what the "specified period of time" is, HPV has indicated to the MTAA on 10 September 2015 that "The specified period of time is detailed within each ITS [Invitation to Supply]. Initially it was a preferential statement, then a 6 months period and more recently 3 months as more suppliers are registering." Registration with Recallnet is a contractual obligation and "Recallnet audits are conducted to ensure suppliers are conforming with their contractual obligations and non-compliance is managed under a category management / supplier performance framework."

In effect, the ability of sponsors and suppliers of medical devices to compete for business in the public healthcare sector in Victoria is conditional upon registering with Recallnet, involving the payment of annual fees to GS1 Australia.

Issues with the Recallnet system

Regulatory background

Most recalls are initiated by sponsors and are voluntary. Recalls for therapeutic goods are governed by the Therapeutic Goods Act 1989 and the Competition and Consumer Act 2010 (which superseded the Trade Practices Act 1974).

According to the Therapeutic Goods Act 1989, mandatory recall provisions can be applied:

- when therapeutic goods are cancelled from the Australian Register of Therapeutic Goods (ARTG); or
- where therapeutic goods are unlawfully supplied in Australia; or
- where therapeutic goods fail to comply with a standard.

The Competition and Consumer Act 2010 contains provisions in relation to the safety-related recall of consumer goods, which are administered by the Product Safety Policy Unit of the Australian Competition and Consumer Commission (ACCC). These provisions empower the Commonwealth Minister responsible for Consumer Affairs to take action when notification is not made of safety-related recalls, or where the recall has not been satisfactorily completed.

The URPTG is recognised by the ACCC as being appropriate to the specialised requirements for the recall of therapeutic goods. Its use is therefore, in effect, obligatory in relation to safety-related recalls of therapeutic goods. Where a sponsor refuses to carry out a recall, or a recall is not carried out satisfactorily, the Minister may order a mandatory recall. Failure to comply with such an order may result in substantial fines. (5)

MTAA's position is that medical technology companies should only have to comply with the obligations under the regulations and follow the TGA URPTG guidance for product recalls.

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Regulatory issues with Recallnet

The functionality of Recallnet is limited such that, in practice, it is not possible to rely exclusively on Recallnet to conduct recalls under the existing regulatory regime. For example:

- Recallnet depends on a single point of contact / email address for recall notifications. Sponsors using Recallnet have contacted several hospitals asking for "a single contact email address" for this purpose, but the majority of them declined, directing the sponsor either to the Purchasing, the Biomedical Engineering or the Nursing Unit Managers.
- Sponsors are required to have evidence that notifications have reached the intended recipients. In the Recallnet system, this is achieved by an "automated read receipt" that the sender of the notification gets from each recipient. As there are still many hospitals and healthcare providers that are not registered (and potentially will not register) with Recallnet, sponsors must often obtain responses separately outside the Recallnet system.
- Recallnet is intended to quickly track existing stock that may need to be removed from a hospital's inventory. However, Recallnet is not linked to hospital inventory systems and therefore it cannot track affected products.
- The Recallnet system requires ongoing administrative maintenance, for instance updating email addresses of contacts within hospitals and other healthcare providers. Since, as noted above, the Recall system does address all relevant regulatory requirements, a sponsor must maintain their own, regulatory-compliant recall system and database as well. Having to maintain two systems in parallel is laborious and duplicative.

The above are specific examples of regulatory issues related to the use of Recallnet. However, HPV continues to mandate registration with Recallnet.

Recallnet is a commercial operation, and MTAA members must register and pay annual fees to Recallnet for performing recalls of medical devices that can be legally done without Recallnet. The additional costs are not just the annual fees charged by GS1 Australia, but also the costs of dedicating resources to enter and maintain data in a particular system while also needing to maintain other systems that are fully aligned to the relevant regulatory requirements.

The MTAA hopes that this paper can provide HPV and other State and Territory jurisdictions with enough information to raise awareness of the limitations of Recallnet and the need to ensure that registration with Recallnet is voluntary.

Possible competition issues

From a competition policy perspective, MTAA considers that it is undesirable for HPV (or any other government body) to mandate the use of particular commercial software by private sector suppliers. Allowing for competition to occur in respect of recall software is likely to facilitate product and service improvements and cost reductions.

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Although MTAA has not explored potential competition law issues in detail, it is concerned that making access to the HPV tendering process effectively conditional upon registration with a commercial service may constitute third-line forcing, which is strictly prohibited by the Competition and Consumer Act 2010. MTAA suggests that this issue be considered further by HPV and other State and Territory jurisdictions.

Conclusion

The MTAA acknowledges that having a "one-stop shop" electronic system to process recall notifications and safety alerts is in principle a good thing. However, instead of "enabling the fast and efficient removal of unsafe or unsuitable products from the supply chain, retailers, hospitals and the wider marketplace" as claimed, the current mandating of Recallnet by HPV only burdens sponsors with administrative red tape and unnecessary additional costs.

In particular, the limitations of Recallnet relative to certain regulatory requirements and the low rate of adoption among healthcare providers translate in a duplication of effort for sponsors because they will have to continue to maintain two parallel systems for recalls and safety alerts.

In view of the above, the MTAA submits that registration with Recallnet should be voluntary.

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Bibliography

1. recallnet.gs1au.org. *www.gs1au.org.* [Online] [Cited: 10 September 2015.] https://recallnet.gs1au.org/healthcare.

2. GS1 Australia Recallnet & GS1 Australia Recallnet Healthcare - Fee Schedule for Australian Users. *http://www.gs1au.org/.* [Online] 1 July 2015. http://www.gs1au.org/assets/documents/services/recallnet/GS1-Recallnet-Fee-Schedule-2015.pdf.

3. About HPV. *www.hpv.org.au.* [Online] [Cited: 10 September 2015.] https://www.hpv.org.au/.

4. Recallnet Healthcare Information for HPV Suppliers. *www.hpv.org.au.* [Online] [Cited: 10 September 2015.] https://www.hpv.org.au/assets/Cabinets/138/Recallnet-information-/2014-08-15-Recallnet-FAQs-Suppliers.pdf.

5. Uniform recall procedure for therapeutic goods (URPTG). *www.tga.gov.au.* [Online] [Cited: 10 September 2015.] https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg.