Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Level 12, 54 Miller St, North Sydney
NSW 2060 Australia
PO Box 2016 North Sydney
NSW 2059 Australia
P (+612) 9900 0650
F (+612) 9900 0655
E mtaa@mtaa.org.au

POSITION PAPER:

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

May 2016 Update

This paper has been prepared by the Medical Technology Association of Australia (MTAA) to provide an update to a previous position paper posted on the MTAA website in November 2015 with regards to Recallnet Healthcare, a.k.a. Recall Health (hereafter referred to as Recallnet), a web portal marketed by GS1 Australia as the online solution for therapeutic goods recalls. GS1 Australia, the official representative in Australia of GS1 Standards, claims IP for this online solution and charges annual fees to subscribers such as public and private hospitals and suppliers of medical technology.

The MTAA is aware, through its members, that GS1 Australia has, for quite some time, been aggressively marketing their proprietary Recallnet web portal to the State health authorities. In 2014 Health Purchasing Victoria (HPV) has introduced mandatory use of Recallnet as a condition for tenders in the public healthcare sector. This situation is highly problematic in that this online web portal operates outside the TGA System for Australian Recall Actions (SARA) and it has no independent oversight. The TGA SARA provides consumers, health care professionals, sponsors, wholesalers, hospitals and retailers with access to information about recall actions occurring in Australia for therapeutic goods. This electronic database holds information on recall actions that have been undertaken in Australia since 1 July 2012.

The industry is concerned about having Recallnet, or any proprietary online solution, mandated via exclusive arrangements with State health procurement authorities. The MTAA believes that the mandatory nature of these exclusive arrangements is contrary to good practice because it favours the commercial interests of the solution provider (GS1 Australia) rather than ensuring an effective and efficient recall process in the best interest of patients, hospitals and suppliers.

Additionally, the action of marketing Recallnet by GS1 Australia creates confusion amongst stakeholders by, on occasion, intertwining discussions on GS1 global standards with those involving Recallnet. Our position on Recallnet appears to have been misunderstood by GS1 Australia as being opposed to GS1 global standards. The industry is supportive of standardization, regulatory harmonization, process streamlining, continuous improvement and automation. Many of our members have already implemented sophisticated Electronic Data Management Systems (EDMS) and Enterprise Resource Planning (ERP) systems.

Medical device recalls must be managed in accordance with the Australian *Uniform Recall Procedure for Therapeutic Goods* (URPTG). Compliance with relevant international standards is one of the best ways to ensure companies manage product recalls quickly and effectively. Evidence of compliance is typically provided through certification to international quality management system standards ISO 13485 *Medical devices - Quality management systems - Requirements for regulatory purposes* or ISO 9001 *Quality management systems – Requirements*, as applicable. These standardized requirements are relevant and effective in promoting patient safety.

Recall systems and processes of medical device manufacturers are audited at least once a year by the TGA or by independent accredited Conformity Assessment Bodies as part of mandatory certification of their quality management systems. Similarly, certified quality management systems of suppliers and distributors of medical devices are audited annually by independent accredited certification bodies. By contrast, there is no independent oversight of Recallnet.

Some of our members who have tried using the recently upgraded Recallnet have reported that its use does not improve the efficiency or effectiveness of medical device recall processes. The MTAA has seen examples of actual recall actions processed in Recallnet. In one example, one year after the supplier initiated the recall notification, only 1 out of 7 recipients of recall notifications completed their action in Recallnet. In another example, six months after the supplier initiated the recall notification, only 1 out of 12 recipients of recall notifications completed their action in Recallnet. Only by using their own recall process and internal systems was the supplier able to successfully complete all outstanding actions in order to meet regulatory obligations.

Following a recent workshop during which GS1 Australia demonstrated the Recallnet upgrade, industry participants have noted a list of pending issues including, but not limited to: persistent poor uptake by both public and private hospitals (less than 50% in Victoria and less than 9% nationally); no uptake, due to costs, and no reasonable expectation for uptake in the future by healthcare professionals who must be contacted in the event of a high-risk medical device recall; manual and laborious processing of recall notifications which offers no advantage over using Excel spreadsheets and company email.

A sticking point remains the Recallnet contractual terms and conditions which basically absolve GS1 Australia of any responsibility if Recallnet system breaks down and recalls cannot be processed for any period of time. The contractual terms and conditions for Recallnet state that suppliers "must maintain a procedure for conducting Recalls and Withdrawals that assumes a lack of access to the Service [Recallnet]", which means that suppliers of medical technology must continue to maintain their own systems, in addition to Recallnet.

GS1 Australia's position in pursuing the mandatory use of Recallnet, with the resulting duplication of tasks and additional administrative burden – not to mention additional charges, will only increase the red tape for sponsors and suppliers of medical technology. In particular for smaller enterprises such red tape would be a drain on their limited resources. There are also concerns that mandating a particular proprietary system without going through a fair and transparent tender process is anti-competitive (*Australian Competition Law - Exclusive dealing, Third line forcing*). Improvements to online solutions for medical device recalls are limited when healthcare authorities and hospitals mandate the use of only one provider. A provider holding the monopoly for online medical device recall solutions has no incentive to improve their system or address ongoing user concerns.

Other countries with mature and sophisticated supply chains for medical devices such as Canada and the United States have steered clear from mandating particular proprietary registries or online solutions. Authorities in these countries stipulate standard requirements (including GS1 global standards), but they do not mandate the use of particular commercial offerings that relate to the standards. Instead, they have a transparent system for provider accreditation.

The MTAA believes there is a place for online solutions for managing recalls going forward, provided such solutions meet the needs of patients, hospitals and suppliers alike. In the interest of maintaining regulatory compliance, and also to reduce red tape, the MTAA looks forward to working with State Health Departments in achieving reliable and sustainable solutions for managing medical device recalls. MTAA and its members would support a fair and transparent accreditation and selection process for solution providers.