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Changes to premarket assessment requirements for medical devices

Version 1.0 – 15th March 2013

Approved for Release

National E-Health Transition Authority

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Key information

Owner:	Mark Brommeyer
Filename:	TGA Changes to premarket assessment requirements for medical devices NEHTA Submission v1.0-150313 Last saved: 22/04/2013 4:16 PM
Review date:	15 March 2013
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Approvals

This document has been approved on the basis that the appropriate input has been obtained during its development.

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1. Executive Summary

The Therapeutic Goods Administration (TGA) is currently undertaking a review of premarket assessment requirements for medical devices. A number of reports and inquiries have emphasized the need to increase the rigour of the TGA's premarket assessment process for higher risk medical devices. This proposal seeks to identify key considerations for improving the premarket assessment process and regulation from the perspective of the National E-Health Transition Authority (NEHTA).

NEHTA is leading the way through the National Product Catalogue (NPC), a central repository of accurate, standardised information about products from large medical devices, to consumables and medicines, along with an eProcurement solution designed to streamline the electronic purchasing process.

Australia's health sector, in particular the Health Jurisdictions, large private hospital groups and major suppliers, is embracing supply chain reform and making significant progress towards an interoperable system that delivers substantial quality and efficiency benefits for providers and consumers. With these foundations in place, the importance of expanding the network to include supporting agencies such as the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Scheme (PBS) and Australian Medicines Terminology (AMT) is critical. This ensures that all parties have the ability to benefit from efficiencies, cost savings and enhanced productivity and in turn continuity of care to their clients.

Due to the unsustainable increases in the cost of providing healthcare, all healthcare providers are searching for ways to reduce costs and deliver efficiencies in their businesses. Implementing global standards inside this Supply Chain reform eliminates the potential for order errors, counterfeit products, stock outs, excessive freight costs and error-prone manual processes.

An accurate and efficient, electronically-enabled network offers major advantages for purchasers and suppliers such as:

- Current, accurate, standardized, medical product data.
- National, standardised method for electronic procurement.
- Secure pricing information available only to nominated trading partners.
- Ensuring reliable continuity of supply with minimum inventory investment.
- Removing inefficient paper-based forms and automating the efficient distribution of product information.
- Reducing order errors and the supply costs associated with invoice reconciliations, credit claims, returns and refused deliveries.

2. Introduction

The National E-Health Transition Authority (NEHTA) is a company established by the Australian, State and Territory governments in 2005 to develop better ways of electronically collecting and securely exchanging health information. NEHTA is an independent company which is state and federally government funded and includes:

- Board of Directors (CEOs of Health Jurisdictions, an Independent Director and an Independent Chair)
- Board Committees
- The Chief Executive Officer
- The Company Secretary
- The NEHTA Organisation

In 2004, Deloitte Touche Tohmatsu was commission to investigate and report on Health Sector Supply Chain Reform and delivered its finding to NEHTA in the report *Recommendations for National ICT Reforms in the Public Health Sector*.

Recommendations for National ICT Reforms in the Public Health Sector findings included:

1. Supply Chain Reform was needed because:
   - Lack of standardised product identification
   - Lack of standardised location identification
   - Multiple product data catalogues being maintained per hospital, per hospital network and per state

2. Poor supply chain costs the health system money:
   - Wrong product ordered/delivered
   - Wrong quantity/poor forecasting and inventory management

3. Automating processes enables supplier and buyer organisations to:
   - Reduce redundant purchasing tasks
   - Improve inefficient work practices
   - Achieve greater accuracy in
   - Procurement and tendering

Over the last six years NEHTA's Supply Chain Programme has designed, developed and implemented reforms including a National Product Catalogue(NPC), Data Synchonisation and Electronic Procurement, aligned with the Australian Standard for Heath Supply Chain Messaging (AS 5023).

NEHTA anticipates that full implementation of the NPC will save the public healthcare sector at least $AUD200 million per annum by ensuring accurate, valid and up-to-date product data, and improved communications and supply chain operations. (Deloittes, 2004)

3. National Product Catalogue

The NPC, hosted by GS1 Australia on GS1net, provides suppliers with a single mechanism to communicate standardised and accurate product and price data electronically to the Australian health departments and private hospital providers.

The NPC records important supply chain and clinical information such as product components, pack sizes, Therapeutic Goods Administration (TGA) risk classification, Pharmaceutical Benefits Scheme (PBS) or RPBS notification and Prostheses Rebate Code. The NPC uses GS1's standard identifier, the Global Trade Item Number (GTIN), as the globally unique primary product identifier for every NPC record. The GTIN provides unambiguous product identification and reduces the risk of product identification errors where internal catalogue numbers may be duplicated across companies. A GTIN is assigned to all products, at all levels of packaging that are supplied to the Australian healthcare sector via the NPC.

4. eProcurement

eProcurement is the use of business to business electronic transactions, instead of manual and paper processes, to streamline the procurement process and increase efficiency. The NEHTA eProcurement Solution is a standards-based national approach for business-to-business (B2B) electronic trading across Australian healthcare organisations.

This solution has two components: (1) messaging structures and syntaxes; and (2) business specifications (also called the Federated Hub Model).

1) Messaging Structures and Syntaxes

NEHTA has developed a standardised set of eProcurement messages. These structures leverage both GS1's global eMessaging standard GS1 XML, and the Australian Standard AS 5023.

NEHTA's eProcurement suite of messages consists of:

- Purchase Order
- Purchase Order Response
- Despatch Advice
- Invoice
- Settlement Advice

The key benefits to be derived from eProcurement include:

- Interoperability between suppliers and purchasers
- Right Product – Right Patient – Right Time and Right Place
- Increased transactional accuracy
- Reduced order errors
- Improved compliance
- Improved payment times
- Timely information for improved purchasing and inventory management.

2) Federated Hub Model

The Federated Hub Model is an industry best practice approach to improve access to business-to-business (B2B) electronic trading for Australian healthcare organisations. The Federated Hub Model specifies the way in which business-to-business (B2B) electronic trading service providers should interact when exchanging electronic procurement messages. This model is based on the messaging standards defined in the NEHTA eProcurement Solution. The Federated Hub Model is commercially important for companies operating in the healthcare supply chain, particularly as they begin to enter into commercial relationships with eMessaging service providers (hubs). This model has been in place in a number of other industry sectors for many years and aims to ensure equity of access to eProcurement by all organisations.

NEHTA Framework of Interoperability is based on:

- Organisational – roles of parties (e.g. buyer, supplier and hub);
- Informational – baseline document for B2B trading (e.g. buyer Messaging Implementation Guideline – MIG); and
- Technical – connectivity between organisations.

5. GS1

GS1 Australia is a not-for-profit organisation that locally administers the global multi-industry system of unique and unambiguous identification and communication for products, services, assets and locations – the GS1 System.

GS1 numbers and barcodes permit organisations of any size to order, track, trace, deliver and pay for goods across the supply chain, anywhere in the world. The National Product Catalogue is hosted on GS1 Australia's GS1net Data pool, which is Global Data Synchronisation Network compliant (i.e. globally aligned to allow interconnection with other data pools).

The GS1 System was developed by GS1 Global Office. It is recognised by the International Standards Organisation (ISO), the European Standardisation Committee (CEN) and the American National Standards Institute.

Today, around one million member companies in 145 countries use GS1 standards as part of their daily business communications, representing over five billion scanning transactions a day.

6. Locatenet

LocateNet is a central repository that enables the exchange of location information between trading partners in the health sector. GS1 Locatenet supports the National Product Catalogue by replacing the current manual processes used by healthcare providers to communicate NPC price locations to suppliers. Due to the move towards the greater use of e-messaging and improved supply chain management, Global Location Number (GLN) management has become an increasing issue in healthcare. GLN's are globally unique 13 digit reference numbers used to identify price-point and ship-to

locations and are allocated by health authorities to hospitals and area health services and private healthcare providers. This location data also cascades down to hospital ward and even ward imprest locations within hospitals.

Benefits provided by GS1 Locatenet for Healthcare are:

- Easier, faster and more accurate eProcurement processes; and
- The NEHTA eProcurement solution use of GLNs in the messaging to identify the ordering party, supplier, ship-to location and billing address.

7. Healthcare Recallnet

GS1 Recallnet is a standardised, industry-driven communication tool enabling organisations of any size including manufacturers, wholesalers, distributors and importers to share real-time product recall and withdrawal notifications with their trading partners and regulators in a secure and efficient manner. Based on global GS1 standards and best practices, GS1 Recallnet standardises and streamlines the recall and withdrawal communication process significantly decreasing business risk and protecting brands.

Healthcare Recallnet aims to deliver an electronic product recall notification system in the Australian healthcare sector, through a phased approach, to improve the speed and accuracy of the therapeutic goods recall process with the aim of improving patient safety. This will cover electronic Recall and Non-Recall Notification processes in Australia; direct notifications from Sponsors to where the recall notification needs to be actioned; direct and structured feedback from recipients to Sponsors for Medical Devices and Medicines.

8. Key Considerations for Medical Device Regulation

NPC

The NPC provides suppliers with a single mechanism to communicate standardised and accurate product and price data electronically to the Australian Healthcare Industry. Therefore NEHTA recommends that each medical device should be listed on the NPC.

GTIN

The regulation of a medical device must include a unique and unambiguous identifier, using a barcode as the data carrier, so that particular product can be traced through the supply chain. NEHTA recommends that each medical device is identified by appropriate GTINs.

RFID

The application of radio frequency identification (RFID) and bar coding of healthcare products has become significantly more prevalent. Internationally, this has been driven by both healthcare brand owners adopting industry best practice, as well as government regulation.

NEHTA's Supply Chain Reform Group (SCRG) recommends Australian and international healthcare brand owners reference and adopt the guidelines contained within the GS1 Automatic Identification and Data Capture (AIDC) Healthcare Implementation Guide v 1.1 (or subsequent updates) available from

the GS1 Australia website
at: www.gs1.org/sites/default/files/docs/gsmp/healthcare/AIDC_Healthcare_Imp_Guide.pdf

RFID will include the GTIN and any other pertinent information such as:

- Patient identification
- Batch number
- Expiry
- Lot number

NEHTA recommends the use of RFID technology particularly for Implantable Devices and those devices that are custom-made for individuals, to ensure automatic identification and data capture of required product information.

ARTGID
The Australian Register of Therapeutic Goods Identifier (ARTGID) is essential information required in the NPC. NEHTA recommends the automation of electronic links between the ARTG common data elements and the NPC.

ANZTPA
The proposed combination of regulatory agencies across Australia and New Zealand and the adoption of NEHTA Supply Chain reform in New Zealand, gives further impetus for the sharing of information, regulation and adoption of common, trans-Tasman medical device data.

9. Summary

The review of premarket assessment requirements for medical devices uncovers an opportunity to include other healthcare reforms pertaining to the supply and procurement of these medical devices. In light of these current reforms it may be worth considering the possibility of including the above requirements as mandatory elements for the ARTG listing.

NEHTA welcomes the opportunity to provide this feedback and would be pleased to engage in further discussions.

10. References

Deloitte Touche Tohmatsu (2004). *Recommendations for National ICT Reforms in the Public Health Sector.* Sydney, Australia.