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Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods

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Executive Summary

The Therapeutic Goods Administration (TGA) is currently evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods. In 2010, the TGA undertook a review of the way it communicates its regulatory processes and decisions, with the aim of improving its transparency. One of the recommendations of the review was that the TGA undertake a feasibility study of a new-to-market risk communication scheme for therapeutic goods. The panel who conducted the review noted that there appeared to be a lack of public awareness of the uncertainties about the safety profiles of medicines early in their lifecycles, and felt that a risk communication scheme for new products could help to encourage public understanding of safety profiles.

This proposal seeks to identify key considerations for evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods 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 health care 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 laborious manual processes.

An accurate and efficient, electronically-enabled network offers major advantage

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s for purchasers and suppliers such as:

- Current, accurate, standardised 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.

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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 'Deloitte: Recommendations for National ICT Reforms in the Public Health Sector'.

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

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

Poor supply chain costs the health system money:

- Wrong product ordered/delivered
- Wrong quantity/poor forecasting and inventory management

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 Team has designed, developed and implemented reforms including a National Product Catalogue (NPC), Data Synchonisation, Electronic Messaging and Electronic Procurement all aligned with 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 AUD$200 million per annum by ensuring accurate, valid and up-to-date product data, and improved communications and supply chain operations (Deloittes, 2004).

National Product Catalogue

The NPC 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.

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

- Current, accurate, standardised 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.

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, hub);
- Informational – baseline document for B2B trading (e.g. buyer MIG); and
- Technical – connectivity between organisations.

GS1

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

GS1 Australia was created to help Australian business enterprises become more efficient; our fundamental role is to allocate GS1 numbers and barcodes, maintaining internationally accepted trading standards. This, in turn, allows Australian organisations to adopt world's best practice supply chain management techniques.

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 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.

Locatenet

Locatenet is a central repository that enables the exchange of location information between trading partners in the health sector. GS1Locatenet 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.

Recallnet

GS1 Recallnet is a standardised, industry-driven communication tool enabling organisations of any size including manufacturers, wholesalers, retailers 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.

GS1 Recallnet is a service by GS1 Australia, a not-for-profit organisation, and is offered on a cost recovery basis. The aim is to ensure it is accessible by all businesses, big and small.

Key Considerations evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods.

National Product Catalogue

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 every therapeutic medical device, pharmaceutical or consumable must be listed on the NPC.

Global Trade Item Number

The regulation of every therapeutic medical device, pharmaceutical or consumable 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 that every therapeutic medical device, pharmaceutical or consumable is identified by GTIN.

Radio Frequency Identification

Radio Frequency Identification 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.

Australia New Zealand Therapeutic Product Agency

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 therapeutic medical device, pharmaceutical or consumable data.

Locatenet

Locatenet is a central repository that enables the exchange of location information between trading partners in the health sector. Global Location Numbers 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. NEHTA recommends the use of GLNs and Locatenet to provide accurate track and trace of all therapeutic medical devices, pharmaceuticals or consumables.

Recallnet

GS1 Recallnet is a standardised communication tool enabling organisations including manufacturers, wholesalers, retailers and importers to share real-time product recall and withdrawal notifications with their trading partners and regulators in a secure and efficient manner. NEHTA recommends the use of Recallnet to provide accurate and timely notifications of therapeutic medical device, pharmaceutical or consumable withdrawal communication process.

Summary

The evaluation of the feasibility of a new-to-market risk communication scheme for therapeutic goods uncovers an opportunity to collaborate with other Healthcare reforms pertaining to the supply and procurement of therapeutic goods. In light of these current reforms, NEHTA recommends the new-to-market risk communication scheme for therapeutic goods take advantage of NEHTA Supply Chains extensive work programme completed to date.

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

References

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