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HIBCC AU POSITION ON DECISION BY NEHTA TO HOST THE NATIONAL PRODUCT CATALOGUE ON EANNET

Background

In late 2004, an organisation called NEHTA (National E-Health Transition Authority) was formed. NEHTA has been formed as a Public Company limited by guarantee, is a joint initiative of the Federal and State Health Departments, and is therefore entirely funded by them. NEHTA has a broad agenda for information technology based initiatives in healthcare. One of their work items is to develop a National Product Catalogue (NPC).

On 20 December 2005, NEHTA issued an industry announcement advising that it would be developing and implementing a National Products Catalogue (NPC), and that this NPC would be hosted on the EANnet system.

The implementation of the NPC was proposed to commence in March 2006, with the expectation that suppliers would need to have their products on the NPC by June 2007.

Issues for Medical Devices Companies

The EANnet system will require manufacturers using the HIBCC product identification standard to:

- Purchase GTIN numbers from GS1¹. The fees are annual fees that depend on the annual revenue and number of company prefixes required by a company.
- Renumber their products with the GTIN standard.
- Subscribe to the EANnet service (operated by GS1 Australia). This fee is dependent on the size of the company (in terms of annual revenue), and the number of products that are hosted on the system.
- Modify existing internal company information management systems, procedures and processes, without incremental benefit to the company.

¹ GS1 was formerly known as EAN International. In Australia it was known as EAN Australia. They underwent a name change in 2005, and became GS1. In Australia they are known as GS1 Australia.

- Integrate their systems (where product master data currently resides) with the EANnet system, requiring additional software acquisition and consulting services.

Issues for Healthcare providers

It is our view that the decision by NEHTA to host the NPC on the EANnet platform will create issues for hospitals, particularly departments where surgical procedures are performed. These issues include, but are not limited to:

- Compromised traceability of product due to the ambiguity created regarding the products' unique identifier. This is because the unique identifier printed, or included in the barcode on the product's packaging will not necessarily be the unique identifier in the EANnet system. This has the potential to create patient safety issues. This can only be avoided if NEHTA also requires that suppliers relabel their products so that the GTIN is included as the unique identifier.
- Costly upgrades for those that have implemented the UPN, particularly for those hospitals that have implemented point of use data capture systems.
- Increased costs incurred by suppliers in conforming to EANnet will likely be passed on to the buyer through increased prices. These costs affect tens of thousands of identifiably different products for many companies, and over half a million such products in total.

Technical Barriers to Trade

HIBCC AU believes that the decision by NEHTA to endorse the EAN system represents a technical barrier to trade, which is in contravention of Section 2.4 of the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement, and with Article 8.4 of the USA-Australia Free Trade Agreement (FTA). This is because:

- The TBT Agreement requires that standardisation bodies ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to trade.
- The TBT Agreement requires that where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops.
- The FTA requires that international standards, to the extent referred to in the TBT Agreement, be used as the basis for technical regulations.
- The HIBCC Standards are internationally recognised standards, endorsed by ISO.

HIBCC AU Position

HIBCC AU's position in relation to NEHTA's decision to implement the NPC based on the EANnet system is summarised as follows:

- 1) Systems used in healthcare for the identification of products in clinical or supply chain applications should be based on the Universal Product Number (UPN). The UPN is an open system that supports product identifiers that are formatted to either the HIBC or

GTIN. It therefore requires no unsafe cross mapping in systems, and is the safest and most efficient means of identifying products for clinical or supply chain applications.

- 2) The EANnet system is a proprietary system that does not support the UPN. The use of the EANnet system in clinical applications will create ambiguity, leading to the increased potential for product traceability to be compromised. This is a major issue for both suppliers and hospitals, with the increased potential to compromise patient safety.
- 3) Systems endorsed by Australian Healthcare should not create technical barriers to trade, and that where standards are endorsed by ISO, that these are also adopted and supported in Australia. HIBCC AU believes that the decision for the NPC to be hosted on the EANnet system creates a technical barrier to trade.

This position is supported by:

Mr Robert Scherini, Managing Director, Johnson & Johnson Medical

Mr Scott Elliott, Managing Director, Smith & Nephew Surgical

Mr Mike Daly, Managing Director, Boston Scientific ANZ

Mr Brent Scott, Managing Director, Stryker South Pacific

Mr John Cooper, Managing Director, Zimmer

Mr Andrew Robertson, Managing Director, Mathys Orthopaedics

Ms Lyndie Driver-Smith, Commercial Manager Australia and New Zealand, Abbott Vascular

Mr Ralph Jennings, Managing Director, ConMed Linvatec Australia

Mr Mark Baker, Country Manager, Hospira - Australia/New Zealand

Mr Mike Wedlock, Managing Director, Bard Australia

Mr Peter O'Neil, Managing Director, AMO Advanced Medical Optics

Ms Carol Fairweather, National Divisional Manager, Welch Allyn Australia

Mr Cameron Harris, Managing Director, DB Health

Mr Gary Hutchinson, President and Chief Executive Officer, Precision Dynamics Corporation

Mr Jeffery Cheetham, Chief Executive Office, SDI Limited

Mr John Nielsen, Managing Director, DonJoy Orthopaedics & TiMax Surgical

Mr Keith Boardman, Country Manager, Australia and New Zealand, AMS Australia

Mr Geoffrey Burge, Ph.D, Managing Director, Beckman Coulter Australia

Mr David James, Manager of Global Operations, Sirtex Medical Limited

Mr Gus Taddeo, Managing Director, Cook Australia

Mr Pat Callanan, General Manager, Advanced Surgical Technologies

Professor Ken Thomson, Director of Radiology, The Alfred Hospital Melbourne

Mr Kirk Kikirekov, President, HIBCC AU Incorporated

Mr Robert Hankin, Ph.D, President and Chief Executive Officer, HIBCC