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White Paper

HIBCC AU Position on EANnet Hosted Catalogue for Medical Devices

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EXECUTIVE SUMMARY

NSW Health through the Peak Purchasing Council (now Health Procurement within NSW Health), has proposed an initiative to aggregate and host product data in a single catalogue based on a proprietary technology platform: the EANnet system.

The EANnet system is not an open system that supports the HIBC (Health Industry Bar Code) as the unique identifier for products. Subscribing to the EANnet system requires a substantial investment by suppliers of medical devices, which we believe to be unjustified.

The EANnet system, whilst having a field for the HIBC in the database, does not accept the HIBC as the **primary identifier**. This means that suppliers that use the HIBC as their product ID of choice are compelled to assign GTIN's to all their products, and cross reference the HIBC. This practice is costly, unsafe, and adds no value to either the supplier or the hospitals implementing systems for processes involving medical devices. Nor does it facilitate automation using Auto-ID technologies. This is because there is no requirement that compels suppliers to cross map their HIBC identifier in the EANnet system. For systems that rely on the barcode for automation, this will result in failed identification for the product when scanned, meaning that hospitals will need to enter data manually.

Another issue that is particularly noteworthy is the re-issuing or re-use of GTIN (Global Trade Item Number) identifiers, because of its poor scalability. The HIBC identifier, on the other hand is highly scalable. Consequently suppliers using the HIBC system are never compelled to re-use numbers, a practice that is commonly performed by suppliers using the GTIN, supported by the General EAN.UCC Specifications for the implementation of the EAN.UCC standards[1].

Furthermore, the EANnet system has not been designed for the specific requirements of medical devices. For example, the Prostheses List, which is a crucial aspect for the supply of implantable medical devices, ought to form an integral component of any cataloguing solution. The fact that the EANnet system does not adequately address this aspect will result in disconnected processes for implantable medical devices.

Finally, it is HIBCC AU's view that there are trade practices issues with the manner in which NSW Health is supporting the EANnet adoption by suppliers. A position by NSW Health to give carte blanche support to a proprietary technology platform, and to use their market influence to coerce suppliers to also take up this service, against their will, and restricting their choice on content aggregation services, has the potential to create a monopoly for the provision of content aggregation services. In this paper, we propose an alternative business model that will still achieve the same intended outcome for NSW Health, without creating potential trade practices issues.

[1] General EAN.UCC Specifications – Numbering and Symbol Marking of Trade Items, Sections 2.1.4.4 – Lead time in re-using a GTIN

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1 Background

NSW Health through the Peak Purchasing Council (now Health Procurement within NSW Health), has embarked on an initiative to aggregate and host product data in a single catalogue. The host for the catalogue, and hence the proprietary technology platform chosen is the EANnet system.

The proprietary EANnet system has been developed for the specific requirements of the grocery industry. Whilst there has been some attempt to make the system relevant for healthcare, HIBCC AU believes that there are significant shortcomings, specifically for medical devices. We believe that it is unreasonable to attempt to adapt a solution designed for another industry, with different requirements, to healthcare and medical devices.

Furthermore, the EANnet system is not an open system that supports the HIBC (Health Industry Bar Code) as the unique identifier for products. Consequently, suppliers that use the HIBC as their product identifier will be required to assign GTIN's to their products, and cross reference the HIBC. This is contrary to decisions made by Standards Australia Committee IT.14.10 – Electronic Messaging, and as subsequently reflected in call for Tender Documents released by NSW Health for supply of medical devices, which states that the identifier can be either a HIBC or EAN.

Aside from the cost and duplication of effort involved, cross referencing is not desirable in healthcare, as it has patient safety implications, with the increased risk of error associated with the maintenance of cross references to many hundreds of thousands of unique parts.

Subscribing to the EANnet system requires a substantial investment by suppliers of medical devices, and the justification for this level of investment is questionable. There does not seem to have been any attempt to quantify any perceived benefits in terms of estimated or expected Return on Investment (ROI), particularly for Small to Medium Enterprises (SME's) but also for large medical devices companies that are already subscribing to HIBCC AU's UPN Repository, and who are deriving benefits from this service with many existing customers.

In consideration of these factors, we can only conclude that the EANnet system will be used by NSW Health for "consumable" products purchased by NSW Health, which includes such items as cleaning products, dressings and other such items that are commonly known as "stock items" – ie they are purchased and held in inventory within hospital warehouses or stores, and that have business requirements more similar to the FMCG industry.

2 Diversity of Products Represented by "Medical Devices"

The medical devices supply chain in Australia is complex. It involves many players, often with competing interests, and the nature of the products is such that a high degree of traceability is required for each product usage instance.

Medical devices include many different types of product. They are often referred to as the "non-pharmaceutical" products that are used in the healthcare supply chain. They range from commodity style products that are inexpensive and used in high volumes within the healthcare supply chain, through to the high end diagnostic and other sophisticated equipment used to carry out tests for the purpose of diagnosis and other treatment options.

It includes the following broad categories of products:

- General medical consumables, such as syringes, gloves, catheters, bandages, sutures, etc.
- Implantable Prostheses and other implants. This includes such items as Intra-ocular Implants, artificial joints, pacemakers and defribulators, artificial heart valves, cardio-vascular stents, cochlear implants and other such implantable devices.
- Medical and Surgical instruments and equipment.
- Medical and Surgical Equipment, including high cost capital equipment.
- Diagnostic equipment and consumables.

In Australia there are some 250,000 items classed as devices, of which more that 85% are imported. Compare this with pharmaceuticals that number approximately 9,000 – 11,000 different products. Furthermore, medical devices typically have a very short life-cycle (2-4 years), compared with pharmaceuticals that typically have much longer product life-cycles (10-20 years).

By way of further comparison, recent estimates by GS1 on the size of their entire EANnet database for the FMCG business states that there are some 146,000 records attributed to some 600 suppliers. This means that the average supplier on the EANnet system has only 246 products. **A typical orthopaedic supplies company alone will have some 15,000 – 30,000 separate products that need to be catalogued.**

The majority of medical devices (86%) are sold to public and private hospitals. Private hospitals are the largest market for medical devices, accounting for 44% of all devices sold. It has been further estimated that the majority of surgery (56%) is now performed in private hospitals[2]. Implantable prostheses are very commonly used in surgical procedures within private hospitals. For example, the following table includes the most commonly performed procedures involving prostheses, and the proportion of these procedures performed on patients electing to be admitted as private patients:

Procedure Type	**Total Separations (Private and Public)**	**Proportion Private**
Coronary artery bypass graft	15,321	50%
Coronary angioplasty	30,906	59%
Hip replacement	28,443	62%
Revision of hip replacement	3,512	66%
Lens insertion	154,393	75%
Knee replacement	28,276	69%
Arthroscopic Procedures	113,905	81%

Source: Australian Institute of Health and Welfare, Australian Hospital Statistics 2003-2004

For many medical devices products (eg implants), the clinical requirements cannot be treated independently or in isolation of the supply chain. Compare this with the FMCG, where tracking of the grocery items purchased do not extend beyond the store in which

[2] Australian Private Hospital Association quoting results from the Australian Institute of Health and Welfare (AIHW), Australian Hospital Statistics 2001-2002

they are purchased. Other than the purpose of sales and marketing of grocery items, there is no other business process intrinsically linked to the purchase of a grocery item.

Catalogues need to be developed in consideration of the business requirements for the diversity of products that exist in the medical devices supply chain, and the systems that such a catalogue is intended to support within private and public hospitals. There are many uses for the catalogue data, beyond the supply chain. Prostheses need to be appropriately recorded in the patient record, costed and billed in the billing systems, registered with implant registries and so on. The catalogue data needs to consider these requirements as well as the supply chain requirements.

It is our view that the proprietary EANnet system has been designed for the supply chain requirements of the Fast Moving Consumer Goods (FMCG) industry, solely for the purpose of the supply chain, without due consideration of the specific requirements of the medical devices industry. Consequently, it falls short in crucial areas for the hospital and their suppliers.

3 Buying arrangements for medical devices

Buying models that exist for medical devices vary depending on the type and nature of the product. For example, consignment stock arrangements are very common for implantable devices, as are "loan set" arrangements for orthopaedic implants used in joint surgery. Understanding these differences is crucial to the development of information management systems that will serve both the hospitals and the suppliers well.

The buying model that exists for medical devices can be summarised by the following:

1) Hospital or healthcare provider purchases stock items, and stores in hospital warehouse for distribution to wards and other departments in hospital on an "imprest" arrangement.
2) Hospital departments purchase non-stock items which are expensed on receipt of goods.
3) Consignment stock arrangements, where the stock is delivered to hospital departments (generally high cost procedure areas such as Theatre or Cath/Lab) by suppliers and stored in hospital premises. This stock is owned by suppliers until it is "consumed" by the hospital.
4) Loan Set arrangements. This generally applies to orthopaedic surgery (although it does apply to a lesser extent with other types of implants as well) where suppliers "loan" to the hospital a set of surgical instruments that are generally non-sterile, and a set of implants (that are sterile or non sterile - many small plates and screws etc are non-sterile) for the purpose of performing a surgical procedure. Under this model, the hospital is billed for those components that are used or "consumed" from the loan set.
5) Capital purchases for high cost medical, surgical and diagnostic equipment.

3.1.1 Stock Item Purchasing

Stock item purchasing is generally undertaken by the "Purchasing Departments" within hospitals. The products purchased under this model tend to be the high volume, low cost items (generally the commodity items that are used on a day to day basis by hospitals such as dressings, gloves, syringes, fluids etc.). Under this model, the following processes usually apply:

1) Hospital staff (nurses, or delegated purchasing officers within each department) complete requisition orders that are submitted to the Purchasing or Stores department.

2) Purchasing department fulfils the requisition orders from supplies held in stock at the hospital warehouse or stores, and decrements the inventory system for the items consumed.

3) Purchasing department places orders with suppliers based on defined min/max criteria for stock held in the hospital warehouse. Generally the purchase orders are placed with suppliers with which the hospital has contracted arrangements.

4) Supplier fulfils orders (places on back-order any items not available in suppliers inventory), and delivers to the hospital's warehouse.

Some hospitals have implemented more sophisticated "imprest" system arrangements. This works on the basis of the hospital having multiple store locations within the hospital, and purchasing officers replenishing these locations as stock is run down at these locations from a central warehouse. Some hospitals are using barcode scanning capability to decrement inventory, and to place requisition orders for products needed at these hospital stores.

3.1.2 Non-Stock Purchasing

High cost procedure areas within hospitals also purchase products that are expensed on the receipt of goods. This generally applies to high cost – low volume items, and can include some implant types (for example guidewires and other products used in radiology or cath/labs). These items are referred to as "non-stock" since they are not held in inventory by the hospital warehouse or stores.

Under this model the following processes generally apply:

1) Procedure areas within hospital use items in surgical procedures. In most hospitals, the nurses are responsible for ensuring that there are sufficient items available at the procedure area location (i.e. where the surgery or other procedure actually takes place).

2) When the nurse determines that items are required, they place a requisition order with the purchasing department for these non-stock items.

3) Purchasing department places a purchase order with the supplier concerned, requests delivery directly to the hospital location that requires the supplies (the theatre or other procedure area).

4) Item is expensed on receipt – which means that the hospital pays for this item following delivery based on the suppliers invoice for the item(s).

3.1.3 Consignment Stock Arrangements

Consignment stock arrangements are very common for prostheses and other implants used in surgical hospitals around Australia. However, consignment stock arrangements also exist for other classes of medical devices as well. These items are generally very high in cost, but low volumes are consumed by hospitals.

Consignment stock arrangements mean that the stock on hand in hospitals is owned by suppliers until such time that items are used, and a purchase order is raised for these "consumed" items.

Under consignment stock arrangements, the following processes generally apply, although they can vary depending on hospital specific arrangements:

1) Suppliers stock hospital locations based on usage of items by the hospital

2) Hospitals use items, and record details of the items used (Catalogue number, Lot/Batch or Serial number), on the patient record. This often involves peeling off stickers provided by suppliers to place on the record.

3) Hospitals then fax the patient record, which includes details of the consumed items to the supplier. The supplier then knows that items have been used. For certain products (eg artificial joints), the arrangement is to replenish what is consumed. Therefore on receipt of the fax indicating usage, the supplier replenishes the items used.

4) Nurses in theatre or other procedure area, prepare the requisitions for used items, and submit to purchasing department.

5) Purchasing department prepares purchase orders and sends to supplier.

6) Supplier invoices the hospital for the consumed items.

Note:

Some hospitals have commenced using "point of use barcode scanning" technologies. Under this arrangement, the hospitals scan the items used, including the lot/serial number, and immediately prepare purchase and replenishment orders for consumed items. Some employ e-commerce messages to send to supplier for consumed item purchase and replenishment orders. This is only the case for a very small number at this stage.

3.1.4 Loan Set Arrangements

Orthopaedic implants generally also include loan set arrangements with hospitals. Loan sets are kits that are put together by the supplier, and include instrumentation and implants that are used for the surgery.

Instruments are generally supplied "non-sterile" which means that they need to undergo sterilization process prior to the surgery taking place. The implants are usually provided as sterile packs, but screws smaller items may be provided as non-sterile and need to go through the sterilization processes of the hospital.

The loan sets include the full range of instruments and sets of different sized implants, screws, plates and other items. Not all items are used during the surgical procedure. Items that are not used are returned.

Under loan set arrangements, the following process generally applies:

1) Surgeon books patient into hospital for procedure, and instructs hospital to order loan set for the procedure.

2) Hospital orders loan set from the Supplier

3) Supplier puts together the loan set, including capturing lot/serial numbers of all items in the loan set.

4) Supplier delivers loan set to hospital (usually via courier). The loan set is often "split" which means that multiple logistical units make up the one loan set. When the loan set is split, the non-sterile surgical instruments are placed in a separate logistical unit to the sterile implants.

5) Hospital receives loan set, and puts the non-sterile components through a sterilization process in the Central Sterilisation Services Department (CSSD).

6) Hospital performs procedure, and records details of implants and other items used in the procedure.

7) Hospital returns loan set to supplier.

8) Supplier receives loan set and scans all items that remain. By deduction, they determine items that have been consumed from the loan set.

9) Hospital prepares Requistions/Purchase orders as for consignment stock arrangements, to send to suppliers.

10) Suppliers invoice the hospital for the loan set components used.

3.1.5 Capital Equipment Purchases or Leases

Medical, Surgical and diagnostic equipment that is considered to be a capital purchase by hospitals, is generally purchased through a tendering process by the hospital. Commercial arrangements that exist for this type of equipment includes, but is not limited to:

- Hospital paying the supplier the full cost of the equipment, (i.e. hospital owns the equipment) and enters into a separate servicing arrangement.
- Various forms of leasing

Consumables used by the equipment are generally a separate buying arrangement, depending on the contracted arrangements with the supplier.

4 Private versus Public Patients – the differences that need to be accommodated

Business processes, specifically for implanted medical devices differ depending on whether the patient is a private patient (within a private or public hospital), or whether they are admitted as a public patient with a public hospital.

Most prostheses sold to the Australian market are listed on the Prostheses List (formerly known as Schedule 5), for the purpose of reimbursement for prostheses used on private patients from the health insurance funds. The current prostheses list under the new arrangements applying from the 31st October 2005, list the minimum (no gap) reimbursement price for prostheses. Some devices will also have a listed maximum benefit. These devices are subject to a gap payable by the patient.

Therefore, the Prostheses List forms an integral component of any cataloguing solution for implantable medical devices. The EANnet system does not have this requirement built into the system. HIBCC AU's UPN Repository does have the prostheses list as an integral component of the database, and therefore benefits hospitals that perform surgical procedures involving implants on private patients. It should be noted that the majority of procedures involving implanted devices are performed within private hospitals.

5 Standards

There is global acceptance of the HIBC product identifier in healthcare. The HIBC standard is an ANSI accredited standard, also incorporated within ISO and CEN. It is also the preferred standard by suppliers of medical devices, specifically those that manufacture products that contain many thousands of parts.

This is because the variable width, alphanumeric design of the HIBC provides suppliers with a great degree of flexibility, is virtually infinitely scalable, and allows suppliers to embed the manufacturers' part number in the barcode.

Because it is highly scalable, suppliers are never compelled to re-use numbers, a practice that is commonly performed by suppliers using the GTIN, a practice

supported by the General EAN.UCC Specifications for the implementation of the EAN.UCC standards[3].

This practice is not acceptable for implantable devices that require uniqueness for the life of the patients to which they are implanted.

The EANnet system, whilst having a field for the HIBC in the database, does not accept the HIBC as the **primary identifier**. This means that suppliers that use the HIBC as their product ID of choice are compelled to assign GTIN's to all their products, and cross reference the HIBC. This practice is costly, unsafe, and adds no value to either the supplier or the hospitals implementing systems for processes involving medical devices.

The Universal Product Number (UPN) concept, that recognises the HIBC or GTIN as the primary identifier is a far more robust design, that is open, more inclusive, and will achieve buy-in by suppliers of medical devices. Indeed the UPN concept has been accepted as the preferred method for product identification by Standards Australia committee for e-commerce (IT.14.10), and has now been implemented in practice by many hospitals as the way forward[4]. Furthermore, many tenders that NSW Health has issued to the market have stipulated preferred compliance to either the HIBC or EAN standard as the product identifier, which in effect is the UPN concept.

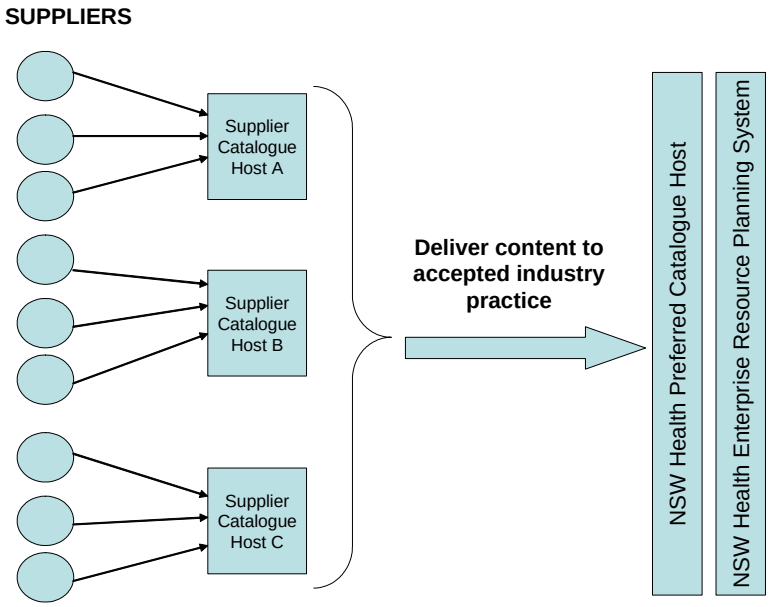
6 Trade Practices and Competition Policy Issues

It is our view that EANnet is a service provider that ought to be subjected to the scrutiny of competition policy. The EANnet system is a proprietary solution. A position by NSW Health to give carte blanche support to a proprietary technology platform, and to use their market influence to coerce suppliers to also take up this service, against their will, and restricting their choice on content aggregation services, has the potential to create a monopoly for the provision of content aggregation services.

We propose the model that better holds to competition policy scrutiny is one where choice of service provider is given to suppliers, and where content delivered to NSW Health's preferred catalogue host is delivered by multiple service providers. This will achieve the same outcome for NSW Health, and with a greater degree of acceptance by suppliers of medical devices. This concept is illustrated in the diagram below:

[3] General EAN.UCC Specifications – Numbering and Symbol Marking of Trade Items, Sections 2.1.4.4 – Lead time in re-using a GTIN

[4] The Alfred Hospital Melbourne, Sisters of Charity and Holy Spirit Health Service Qld, The Epworth Hospitals, John James Memorial Hospital, ACT Health have all implemented the UPN in their point of use data capture systems for the recording of medical devices used in surgical procedures.



Under this model, suppliers are able to choose the content aggregator or service provider that they would prefer to work with, based on the perceived value that the service provider or solution brings to them. Under this scenario, the provision of content aggregation services is not monopolised, and both NSW Health and suppliers benefit through improved level of service and competitive prices.

7 Cost vs Benefit of subscribing to EANnet

We also contend that NSW Health has not attempted to establish a business case for suppliers to sign up to the EANnet service. A properly constructed business case would establish the costs and benefits (tangible and intangible) of alternative options and models, and the risks associated with all options.

8 HIBCC AU Position

1. The EANnet system does not address the specific requirements of medical devices companies.
2. The EANnet system seriously disadvantages medical devices companies that prefer to use the HIBC as the product identifier. This is because these companies will be required to also issue GTIN's for every item sold, and cross reference to their preferred identifier – the HIBC. The design of the EANnet system is therefore not acceptable.
3. HIBCC AU contends that cross mapping is costly, and increases the risk of errors and patient safety.
4. HIBCC AU supports systems that are designed to incorporate the Universal Product Number" (UPN) as the unique and primary identifier for a product. The formats that are acceptable in the UPN include the HIBC and GTIN formatted indentifiers.
5. The EANnet system is a proprietary system, that sells cataloguing and content aggregation services to customers. There are other service providers, including HIBCC AU that provide similar services. Such services should be subjected to competition policy, and NSW Health and other large health

providers with significant market power should adopt models that are supportive of competition policy.

6. The preferred model of HIBCC AU is one where supplier choice of service provider is permitted, so long as content is delivered to NSW Health to a preferred industry accepted standard. This preferred industry accepted standard should address the specific requirements of the different categories of medical devices (such as implantable devices).