Health Industry Business Communications Council of Australia
HIBCC AU Incorporated
PO Box 613
Haberfield NSW 2045
Tel: 61 2 9797 0883
Fax: 61 2 9797 8441
www.hibcc-au.com.au

White Paper

A Unified Approach for Product Identification via the Universal Product Number (UPN) is essential for Medical Devices in Australian Healthcare

May 2005

EXECUTIVE SUMMARY

The medical devices industry, on a global scale has accepted the Universal Product Number (UPN) as the preferred method for product identification. The UPN is an approach where the product identifier can be formatted using either the Health Industry Bar Code (HIBC) format, or the European Article Numbering(EAN) format. Companies globally conform to these standards, as they are recognised by the major standards organisations, including ISO, CEN and ANSI. The UPN approach is also recognised by the major industry bodies representing the medical devices industry, including AdvaMed, Eucomed and the MIAA in Australia.

Medical devices are different to other products distributed into healthcare, as are pharmaceuticals. In Australia, Information Technology strategies for pharmaceuticals have long been addressed by groups' expert in this business. This is because pharmaceuticals have requirements that are different to other supplies purchased by hospitals. Health Industry Business Communications Council Australia(HIBCC-AU) argues that medical devices also have their unique requirements, and are quite different to pharmaceuticals in terms of the nature and diversity of the products marketed and sold, the business models that exist, and the manufacturing and distribution of these products globally.

This paper provides an overview of the medical devices business in Australia, and presents the case for maintaining a unified standards approach (i.e. the UPN) for medical devices as the most practical, reliable and safe means of product identification, satisfying the unique requirements of the medical devices industry while meeting the needs of other suppliers to the medical industry. In summary, the reasons that the UPN is desirable are:

- The majority (more than 85%) of medical devices products marketed and sold in Australia are imported. This includes to the packaging of the product (i.e. the products are not repackaged in Australia). The product identifiers assigned to these products is assigned by the manufacturers overseas. For medical devices, it is crucial that the same identifier applies globally for traceability[1].
- The HIBC standard is accredited by ANSI and incorporated within ISO and CEN standards. Manufacturers will continue to use HIBC as their preferred standard, since it is an open system; it is alpha-numeric which suppliers believe to be inherently safer; and provides a virtually unlimited number of identifiers without the need to recycle numbers, which is possible under the EAN system. This aspect is absolutely crucial for implanted devices that need to be traced for the life of the patient.
- Supporting a position other than the UPN will result in unnecessary additional costs to be incurred and delays to the implementation of systems that improve the management of medical devices in healthcare.
- Re-labelling or over-labelling of medical devices to give them another identifier presents significant regulatory issues, and it is not feasible for many devices which are imported as sterile products.
- The UPN has gained acceptance in Australia for medical devices, and it is increasingly being specified in tenders for the supply of medical devices.
- Many large hospitals have implemented systems that accommodate the UPN, and rely on the UPN Repository for accurate identification of the products when used in procedures.

[1] ISO 13485:2003 – Medical devices – Quality management systems – Requirements for regulatory purposes, has strict traceability requirements for medical devices throughout the global distribution chain.

TABLE OF CONTENTS

1 Background to the Medical Devices Industry

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 Intracular Implants, artificial joints, pacemakers and defribulators, artificial heart valves, cardio-vascular stents, and cochlear implants.
- Medical and Surgical instruments and equipment.
- Medical and Surgical Equipment, including high cost capital equipment.
- Diagnostic equipment and consumables.

The medical devices sector is characterised by the following key attributes:

- Products are required to be registered or listed with the Therapeutic Goods Administration (TGA) prior to selling on the Australian Market.
- Implantable prostheses are generally listed on the Commonwealth Government Schedule 5 for Prostheses. Items on this schedule are approved for private health insurance claims. Currently the prices rebated by health insurance to the hospitals are based on negotiated rates between the suppliers and the health insurance funds. However, this arrangement is in the process of changing in 2005. Under the new arrangements, prices will be negotiated by clinical advisory groups that will report to the Prostheses and Devices committee for approval by the Federal Minister for Health. This process is currently underway.
- A large proportion of medical devices are sold to the market on a "consignment" model. There are also "loan set" arrangements for some products – mainly for products used in orthopaedic surgery.
- A subset of the medical devices industry includes capital equipment, which is very sophisticated and of high cost. Some diagnostic equipment uses consumable products such as reagents and other products necessary for the conducting of diagnostic tests.
- The majority of medical devices are imported, mainly from the USA, but also from European and Asian nations. They are generally imported in their "finished good" state, and are not modified in any way in Australia, including the packaging.

The product differences that exist within the medical devices industry, warrant further segmentation for the purposes of supply chain, business processes and unique healthcare considerations.

Furthermore, in terms of product identification, medical devices in general use the two internationally recognised identification standards, Health Industry Business Communications Council (HIBCC) and EAN. The HIBCC standards in particular are dominant in the implantable prostheses category, with many of the major suppliers all using this system.

2 The Medical Devices Supply Chain

The medical devices and diagnostics industry market segment is made up of companies that manufacture, sell and distribute medical, surgical and diagnostics products. These products are also often referred to as the "non-pharmaceutical" products that are used or consumed within Australian hospitals, day surgeries, pathology, medical centres and other similar establishments.

The industry in Australia is made up of more than 1,100 companies. However, 85% of sales revenue from all companies is made up from approximately 10% of these companies (ie approx 100 companies make up 85% of sales revenue for this market segment)[2].

It has also been estimated that 85% of products distributed in the market segment are imported, with the bulk of these (60%) manufactured in the USA[3].

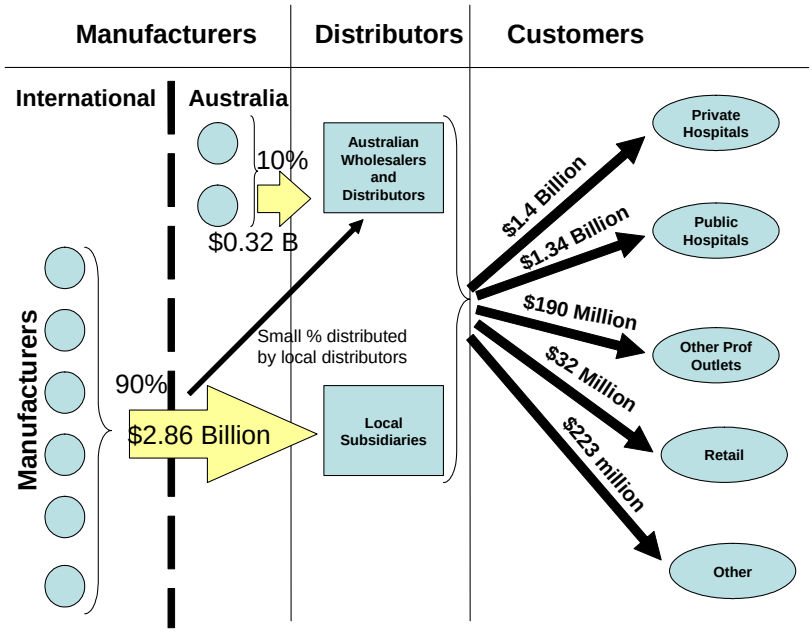
Number of Companies	***1,100***
Number of Employees	10,000
Annual Sales Revenue ($'000)	3,180,000
Top 10% of Companies Annual Sales Revenue ($'000)	2,700,000
Top 20 Companies Annual Sales Revenue ($'000)	2,148,000

2.1 The medical devices "value chain"

The diagram on the following page illustrates the value chain for the medical devices segment. Note that these figures include the entire medical devices segment, which includes diagnostic, general medical consumables, surgical instruments and equipment, and prostheses and implants.

The Transport function is generally fulfilled by specialised third party transport companies, such as Toll Logistics. However, some suppliers are now using third party logistics providers such as Exel logistics who manage the entire logistics function, including warehousing, logistics and transport. The value of this industry is not known at this stage.

[2] Medical Industry Association of Australia (MIAA)
[3] ibid



The majority of supplies are distributed by the local subsidiaries of the manufacturers. A smaller, but not insignificant amount is distributed by Australian based businesses that are importers of products for overseas based manufacturers.

There are also situations where local subsidiaries use Australian Based distributors to sell product ranges, depending on the sales force capability of the local subsidiaries and the Australian Based distributors.

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[4]. 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

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

2.2 Buying Models

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 where suppliers "loan" to the hospital a set of surgical instruments that are generally non-sterile, and a set of implants (that are 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.

2.2.1 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). 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.

2.2.2 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 on surgical procedures. In most hospitals, the nurses are responsible for ensuring that there are sufficient items in store at the procedure area location (i.e. where the surgery or other procedure actually takes place).
2) When 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).

2.2.3 Consignment Stock Arrangements

Consignment stock arrangements are very common for prostheses and other implants used in surgical hospitals around Australia.

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:

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 sophisticated 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.

2.2.4 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 provided as sterile items.

The loan sets include the full range of instruments, 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 (the instruments) 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.

2.2.5 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.

2.3 Implantable Prostheses unique requirements

Implantable prostheses are subjected to requirements that are quite unique in a number of ways:

2.3.1 Schedule 5 Benefits Payabel List

As with pharmaceutical benefits scheme (PBS), implantable prostheses are listed on a similar scheme, called Schedule 5. There are however many differences with the PBS, the main difference is that Schedule 5 rebates are only applicable to patients that elect to

have their treatment performed "privately" – i.e. the treatment is paid in full or in part by the patient's private health insurance scheme. The procedure can be performed in either a public or private hospital. The PBS is applicable to rebates for pharmaceuticals under Medicare.

2.3.2 Consigned and/or loaned to hospitals

Implantable prostheses are often supplied to hospitals on consignment, which means that the supplier "owns" the device until such time as the device is used or implanted to a patient. The purchasing process occurs after the item has been consumed.

This arrangement requires a much greater level of management of consigned stock, and a higher degree of traceability is required by hospitals and suppliers.

2.3.3 Tracking by Lot/Batch or Serial number

Implantable prostheses, due to their nature, need to be traced to the patient to whom the device is implanted. This requires that the lot/batch or serial number of the device needs to be recorded on the patient record, as well as the product ID. For this reason, the majority of implantable medical devices include barcodes that contain this "secondary" information. Conversely, pharmaceuticals do not have secondary barcodes on the individual sales unit, since most pharmaceuticals are distributed to retail pharmacy, and are coded with EAN 13 only (which is just the product ID).

2.3.4 Billing arrangements

Implantable prostheses have unique billing arrangements between suppliers and hospitals, and between hospitals and health funds. At the current time the price is set by the Schedule 5 list. Under new arrangements which are in the process of negotiation, minimum and maximum benefit prices will be set for devices on schedule 5, and hospitals may be able to enter into separate contractual arrangements with suppliers. In the case of private hospitals, it may be possible for the hospital to make a margin on the device used in a procedure, as the price that they negotiate with a supplier for a device, may be lower than the amount rebated by the health fund for the same device.

2.3.5 Implant registries

There are currently two implant registries in Australia that also require data on implants performed to patients to be sent to them. The implant registries are the National Joint Replacement Implant Registry, and the heart valve registry. Whilst the registries are optional, most hospitals do report their cases to these organizations. Hospitals fax completed forms to the registries, and data entry staff enter this data to their databases.

2.4 Differences Medical Devices compared with Pharmaceuticals

As inferred in the previous sections in this paper, there are numerous differences between pharmaceutical products and medical devices:

- There are significant differences in the way that medical devices products are distributed and sold. Most products are distributed directly to hospitals, and many are on consignment stock arrangements (especially prostheses products). 70% of pharmaceuticals are distributed to retail pharmacy. The 30% that are distributed to hospitals, are generally distributed to the hospital pharmacy or store, and not the multiple care locations (such as theatre, cath/lab etc), that exist in hospitals.

- Medical devices (especially prostheses) products require tracking to patient. This means that products need to be identified, and the Lot/Batch or Serial number of the product needs to be recorded on the patient record. Because of this

requirement, medical devices will generally include this "secondary" information in a standard barcode. Pharmaceutical's, on the other hand, do not require the same degree of traceability, and do not include secondary information in a barcode. Most pharmaceutical products are barcoded using the EAN 13, which is just a product identifier, and does not include lot/batch or other secondary information.

- There are only around 9,000 – 11,000 pharmaceutical products available in Australia. There are more than 250,000 medical devices. Furthermore, pharmaceuticals have a very long life cycle (10-20 years), compared with a very short life cycle for medical devices (2-4 years).

- 85% (or greater) of medical devices are imported (60% from the USA).

3 Product ID Standards used on Medical Devices

3.1 HIBCC Standards

The HIBC Supplier Labelling Standard is an ANSI accredited standard that has been implemented by more than 1,500 medical devices companies globally, including many of the large multi-national medical devices suppliers, such as Johnson & Johnson Medical, Stryker, Zimmer, Smith & Nephew Surgical etc.

The standard includes a comprehensive definition of the product identifier component of the barcode, as well as the secondary barcodes which includes dynamic and variable data such as Lot/Batch, expiry date, quantity and other important data elements.

The product identifier includes 4 key components:

1) The Labeller Identification Code (LIC). This is a 4 character alpha-numeric code assigned to the supplier by HIBCC, and is unique to the supplier.

2) A variable width product number assigned by the supplier. This is a variable width, 1-13 character alpha-numeric string assigned by suppliers. Suppliers using the HIBC standard usually use the part number assigned to the product. Embedding the part number in this way is an added safety feature of the HIBC.

3) A packaging level indicator (0-9). Each different package level, from unit of issue through to the outer containers can be identified using the packaging level indicator. This effectively gives each package level a unique identity.

4) A mathematically calculated check character is placed on the end of the code. The purpose of this is as an added security measure for scanning applications. Scanners are programmed to do an internal check of the check character, and if it does not match the check sum included in the barcode, the scan results in a "failed scan".

The standard is consistent universally – i.e. there are no variations depending on the country or region that the standard is used.

Key features of the standard include:

- Alpha-numeric design. Medical devices suppliers prefer alpha-numerics, because they are inherently safer than all numeric identifiers, and provide a much greater number of identifiers than the fixed width, all numeric identifiers used by EAN. This means that assigned identifiers are never re-used, because suppliers have a virtually indefinite number of identifiers. EAN identifiers, on the other hand are

often re-used, due to the need to preserve their numbers. In fact the 2005 General EAN.UCC Specifications permit the re-use of identifiers[5]

- Carrier independent. Suppliers are free to choose the data carrier that best suits their products. The carriers used are ISO endorsed carriers, such as Code 128, Code 39 and data matrix.

- The secondary barcode in the HIBC has a check sum calculation performed for added security. The EAN standard does not perform a check digit calculation on secondary data.

- For added security and safety, the HIBC standard includes a link character between the primary and secondary barcodes, where the primary and secondary barcodes are separated, i.e. not concatenated - which is the majority of products. The EAN standard has no such design, with the secondary barcode having no reference to the primary barcode.

The examples below illustrate the application of a typical HIBC formatted barcode in the separated and concatenated (joined) formats.

The top barcode is the primary barcode which is the product identifier. The bottom barcode is the secondary barcode which includes expiry date, and lot/batch data.

Primary and secondary data can be concatenated (or joined) into a single barcode. The barcodes above could therefore be represented in a single barcode as follows:

The HIBC standard is also recognised by CEN and ISO. A recently released ISO Standard, *ISO 22742: Packaging – Linear bar code and two-dimensional symbols for product packaging*, incorporates the HIBC standard.

The HIBC standard is endorsed by major medical devices industry organisations globally, including:

- The Medical Industry Association of Australia (MIAA)

- Advamed (USA)

[5] 2005 General EAN.UCC Specifications Section 2.1.4.4 – Lead time in re-using a GTIN

- Eucomed (Representing all medical devices industry groups in Europe)

For further information about the HIBC standard, refer to ANSI/HIBC 2-1997, The Health Industry Bar Code (HIBC) Supplier Labeling Standard.

3.2 EAN Standards

The most common EAN standard used on medical devices is the EAN 128 standard. This standard includes "Application Identifiers" (AI's) to identify data components in the barcode. Typical application identifiers include (01) – for Product ID, (17) for expiry date, (10) for Lot/Batch number.

The EAN.UCC identifier is referred to as the Global Trade Item Number (GTIN). It is an all numeric code that can be either 8, 12, 13 or 14 digits, depending on the application. For medical devices, most companies that have adopted this standard use the 14 digit format, however, this can vary depending on the country of manufacture and other factors.

There are some medical devices companies that use the EAN.UCC standards. These tend to be European based companies, with manufacturing operations in Europe.

The examples below illustrate the application of the EAN 128, which is the most common format for medical devices, in the separated and concatenated format.

As with the HIBC, the top barcode is the primary barcode which is the product identifier. The bottom barcode is the secondary barcode which includes expiry date, and lot/batch data.

Primary and secondary data can be concatenated (or joined) into a single barcode. The barcodes above could therefore be represented in a single barcode as follows:

For further information about the EAN.UCC product identification standards, refer to 2005 General EAN.UCC Specifications.

3.3 Other Standards

There are a small number of suppliers of medical devices that do not comply to the two main product identification standards (HIBC or EAN). These suppliers use internal proprietary systems. HIBCC discourages this practice.

4 The Universal Product Number (UPN)

The UPN is a concept that was created by HIBCC, and allows products to be unambiguously identified by their unique HIBC or EAN identifier. The UPN can therefore be formatted using the HIBC system, or the EAN system.

The reason that this is possible is that the HIBC is an alpha-numeric code, and the EAN is always a fixed length all numeric code. This means that provided that the primary identification field in databases is formatted as an alpha-numeric, 20 character field, the HIBC and EAN codes can co-exist in database systems, without the risk of duplication.

Furthermore, modern barcode scanning systems are able to auto-discriminate the barcode symbologies that are used, which means that irrespective of whether the product is coded with the HIBC barcode, or the EAN barcode, scanners are able to read the data, and reference the information in database systems that provide the product information and attributes.

The UPN has gained widespread acceptance globally, including by:

- Health Industry Distributors Association (HIDA)
- Eucomed
- MIAA
- Advamed
- USA Department of Defense
- Efficient Healthcare Consumer Response (EHCR), one of the most significant studies undertaken in the healthcare supply chain stated that: "The development of the UPN as the healthcare industry standard for product numbering will enhance the accuracy and efficiency of transaction processing significantly.

In Australia, the UPN has been put into practice by a number of very large hospitals, including:

- The Alfred Hospital in Melbourne
- The Canberra Hospital (ACT Health)
- Sisters of Charity and Holy Spirit Health Service Qld, including Holy Spirit Northside and St Vincent's Private Hospital Toowoomba.
- The Epworth Hospital (Richmond and the New Epworth Eastern)

There have also been numerous tenders for medical devices that have specified compliance to either the HIBC or EAN standards over the past few years. This includes tenders issued by NSW Health and ACT Health. ACT Health has also written letters to the major suppliers of medical devices encouraging them to join HIBCC AU and subscribe to the UPN Repository.

5 Data Synchronisation and Product Registries

Product data synchronisation between suppliers and providers (hospitals etc) is fundamental to the success of "Auto-ID" technologies. Synchronised data includes the product identifier, which enables scanning technologies to be implemented, but it also

provides accurate and reliable information to be shared across the supply chain, to ensure that transactions between trading partners are streamlined and error free.

Typically, the methods employed to synchronise data between trading partners include:

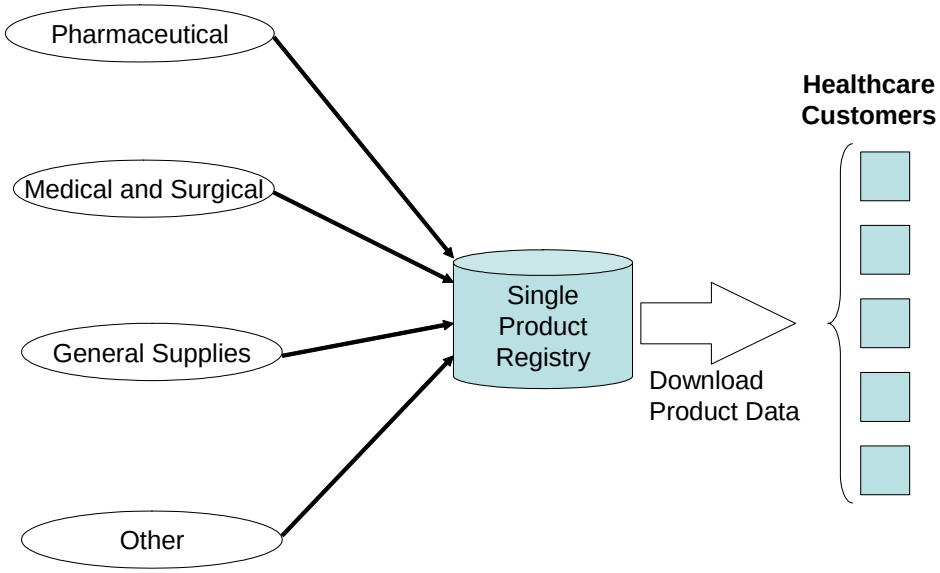
- Suppliers provide in an agreed electronic format (usually spreadsheet or CSV file) their product data to their customers.
- Suppliers and their customers subscribe to a product registry service, such as the UPN Repository or EANnet.
- Suppliers send data to their customers by Electronic Data Interchance (EDI) – this is the system to system approach.

5.1 The 'Single' Product Registry

There are some proponents within healthcare that support the idea of a single product registry for all categories of products: Pharmaceutical, Medical and Surgical, General supply, hardware etc.

This model would need to cater to all the differences that exist within the different product groups, and of the business models. For example, the business requirements for pharmaceutical products are different to implantable prostheses, and these differences would need to be built into such a system.

The diagram below illustrates the concept of the "single" product registry.



5.2 Industry Specific Registries

Industry specific registries, such as the UPN Repository which caters to the medical devices industry, work in a similar way to the single registry concept, except that they are targeted to an industry sector.

The advantage of industry specific registries is that they are much more focused in the development of requirements for the industry sector that they cater to, and have a natural advantage in gaining the support of many players in the same industry.

5.3 The 'Hybrid' model – a practical and commercial reality

The hybrid model is one where data synchronization occurs under the different available models, depending on agreements (commercial or otherwise) reached by the trading partners. Under the hybrid model, industry specific registries co-exist with "point-to-point" EDI transactions for synchronizing product data. Under the hybrid model, standards are a crucial requirement to ensure that product data for industry sectors is universally applied, irrespective of the means by which the trading partners use to share this data.

Industry Specific registries under this model would need to sell the business case for data aggregation to their customers. Such registries would therefore increasingly be required to provide other value added services that benefit their subscribers.

Furthermore, this model provides a competitive incentive and environment to such service providers that ultimately benefit the healthcare consumer.

6 Drivers for Product ID and data synchronisation for medical devices

6.1 Food and Drug Administration (FDA)

The FDA in the USA is currently considering proposals for the mandatory barcoding of medical devices to a standard product identification system, either HIBC or EAN. Should this proposal be legislated by the FDA, this would most certainly create the driver for compliance to the standards on a global scale.

However, the medical devices industry through Advamed in the USA does not support these proposals, and is actively lobbying against the mandatory barcoding of medical devices, preferring instead the voluntary system. The Advamed position was recently articulated in a press release on the 19th May 2005:

Evidence Lacking that Bar Codes on Medical Devices Improve Patient Safety; Industry Supports Voluntary System

The medical technology industry has long supported the voluntary use of automatic identification technologies - including bar coding and radio frequency systems - on medical devices where it is beneficial to patients and technically feasible.

Recent calls for FDA to require a bar code identifier on all medical devices represent a solution in search of a problem and demonstrate a lack of understanding of the diversity and complexity of medical technology.

Last year, FDA mandated that bar codes be placed on most prescription and certain over-the-counter drugs to help improve

patient safety by reducing the number of medication errors in hospitals - responsible for approximately 7,400 patient deaths per year.[1]

While medication errors are a clear and significant problem that can be addressed by bar coding, proponents of the technology can point to no similar health care threat that would be solved by placing bar codes on medical devices. The bottom line is that there is no evidence that extending FDA's bar code requirement to medical devices will result in any demonstrable patient benefit.

Drug Solutions Do Not Apply to Medical Technology

Asking FDA to apply to medical devices a remedy specifically intended to address a drug issue reinforces the faulty assumption that drugs are just like medical devices.

Bar coding works for drugs because, for the most part, they look alike and have similar packaging. Using bar codes allows for a machine to accurately and quickly read a drug label and thus reduce the potential harm from human misreading.

The diversity and complexity of medical devices, on the other hand, makes the mandatory application of bar codes infeasible and, in some cases, impossible.

- *Devices come in all sizes, from vascular stents no bigger than a thumbnail to computed tomography scanners that can take up an entire room.*
- *Medical devices can be packaged individually or by the hundreds; composed of a wide range of materials requiring various sterilization and storage needs; and designed for single-use or multiple-use, requiring reprocessing.*
- *Some devices have specially treated surfaces, such as finely polished surgical implants, which could be rendered useless if a bar code were required to be affixed or etched upon them.*

Mandating the use of bar codes also fails to take into account the rapid evolution of auto-identification technology. Today's cutting edge system could very well be obsolete tomorrow.

Under the current voluntary system, medical technology manufacturers and customers agree on appropriate automatic identification standards, packaging levels and devices to meet customers' needs. Manufacturers already have auto-identified thousands of devices will continue to work with customers to decide which other products should be auto-identified.

The medical technology industry recognizes the utility of auto-identification systems and has invested substantially in bar coding technology, in particular, where real benefits to patients and users can be realized.

- *Infusion pumps, for example, include bar code technology to ensure the safe delivery of drugs. These devices include bar*

code readers to scan the patient ID bracelets, caregiver ID badges, and the unique identifier on the drug label to ensure the "five rights" of drug delivery: right patient, right drug, right dose, right time, and right route. Having a mandated bar code on the infusion pump itself would add nothing except cost.

- *Large volume laboratory analyzers also utilize bar code technology to ensure the right test results are matched with the right patient. These devices can scan bar codes on patient sample containers and each of the reagents, mixing, and analysis chambers. he analyzer itself does not need a bar code label to ensure patient safety.*

[1] *Institute of Medicine (IOM), "To Err Is Human: Building a Safer Health System", 2000*

6.2 Point of Use Data Capture systems

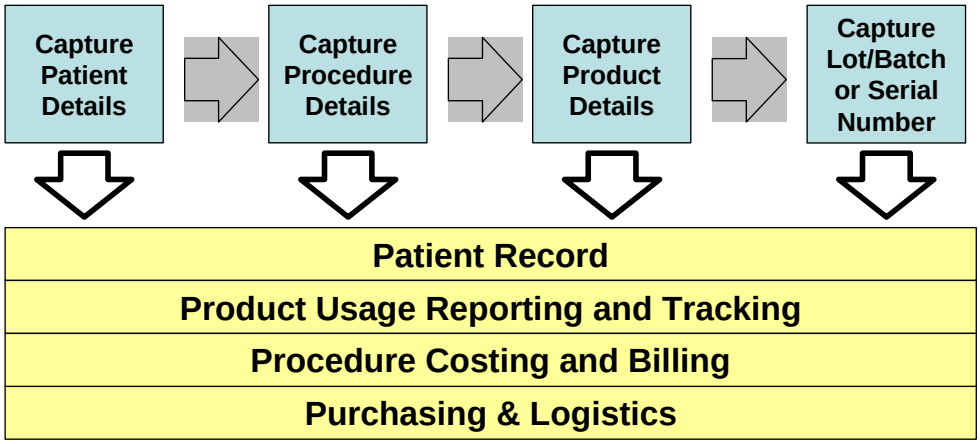
The most significant driver for standardization in product ID and synchronization of data for medical devices, is the increasing number of hospitals that are implementing point of use data capture systems.

There are a number of large Australian hospitals that have implemented, or are in the process of implementing point of use data capture systems using Auto-ID technologies. These systems capture details about the medical or surgical procedure taking place, including the capture of medical devices used on a patient during the procedure. Medical devices used are captured by barcode scanning the manufacturers' standard barcodes.

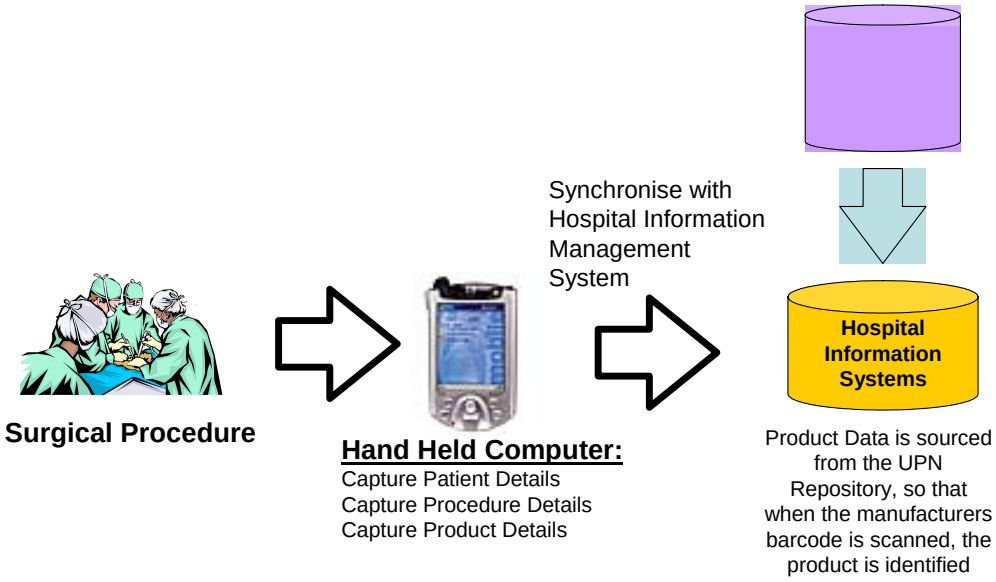
The reason that these systems are being implemented by hospitals includes:

- The need to accurately and reliably trace medical devices used in procedures directly to a patient
- More accurate and efficient costing of procedures
- Improved management of the rebates applicable to implantable medical devices.
- Simplification of the billing and ordering of medical devices, and improved management of consignment stock (Most implant products are supplied on consignment to Australian hospitals).

The concept in the implementations is identical, since the objective is always the same, as illustrated by the diagram over the page.



These implementations use mobile computers within the operating room environment to capture this information, and synchronises this information once captured with the hospital information management systems. The diagram below illustrates conceptually the systems.



7 Regulatory and other issues

Medical Devices marketed and sold to the Australian Market are required to be listed or registered with the TGA. The regulatory framework that applies to goods registered or listed with the TGA is the Therapeutic Goods Administration Act. This Act places strict requirements on labelling of products. In general, re-labelling and over-labelling of goods administered by this Act is not permissible, unless the suppliers obtain appropriate licences (including Good Manufacturing Practice licences – GMP). Most suppliers of medical devices in Australia are importers, and obtaining approvals for re-labelling or over-labelling is costly and not viable.

Many devices are also imported as sterile products, and the original packaging cannot be tampered with, without risking compromising the sterility of the product. Re-labelling or over-labelling products that are sterile, is very costly, and not viable.

8 Concluding Comments

This paper has provided an overview of the medical devices supply chain in Australia, the unique business requirements, and the product identification standards used. HIBCC AU supports the UPN approach to product identification of medical devices. The UPN approach supports the use of HIBC or EAN formatted product identification systems. The UPN Approach is:

- Standards based, and supported by the major standards organizations including ISO, CEN and ANSI.
- Accepted by medical devices industry associations globally, including Advamed, Eucomed, and MIAA.
- In widespread use globally by medical devices companies.
- Practical and involves the least amount of cost to implement for the healthcare industry in Australia.
- Accepted by hospitals and suppliers in Australia as the recognized approach to product identification.
- Implemented by many hospitals and suppliers in their trading transactions.
- Open and inclusive, and offers the best alternative for a truly integrated and streamlined global supply chain.