Joint MTAA, IVD Australia, ADIA and AusBiotech Policy Paper:

UDI Implementation in Australia May 2018

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

ADIA Australian Dental Industry Association

AusBiotech AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

IVD AUSTRALIA

Contents

1. Executive Summary

Medical device regulators world-wide are adopting a unique device identification standard - the Unique Device Identification (UDI) - to improve identification and traceability for medical devices through their distribution and use. Medical device traceability is essential to ensure effective post-market safety-related activities in a globalized economy, such as incident reporting and targeted field safety corrective actions.

The UDI was initially introduced in September 2013 by the U.S. FDA[1] and its implementation continues to be phased in[2]. The UDI has also been adopted by the International Medical Device Regulators Forum (IMDRF) thus becoming an internationally recognised standard for unique medical device identification[3].

The UDI consists of a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. UDI on a device label or package is composed of two parts, defined in the IMDRF UDI Guidance as follows:

- **Device Identifier (UDI-DI)** – a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDI database; examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC, ISBT 128-PPIC (Processor Product Identification Code);
- **Production Identifier (UDI-PI)** – a numeric or alphanumeric code that identifies the unit of device production; UDI-PI include serial number, lot/batch number, Software as a Medical Device (SaMD) version and manufacturing and/or expiration date;

The new European Medical Device Regulations (EU MDR) and In Vitro Diagnostic Medical Devices Regulations (EU IVRD) adopted in 2017 include UDI provisions in Article 27 (MDR) and Article 24 (IVDR) *Unique Device Identification system*; Article 28 (MDR) and Article 25 (IVDR) *UDI database*; and Article 29 and Article 26 (IVDR) *Registration of devices*.[4,5]

In Australia, the current most-commonly used approach to market authorisation remains acceptance of the approval issued by a European notified body[6]. Over 90% of medical devices included in the Australian Register of Therapeutic Goods (ARTG) rely on CE marking certification issued in Europe. Therefore, it is imperative that Australian regulations remain closely aligned with the EU regulations and international best practice that enables the world-wide exchange of medical device data.

---

[1] U.S. Federal Register, Unique Device Identification System – Final Rule: https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system

[2] FDA Compliance Dates for UDI Requirements: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ComplianceDatesforUDIRequirements/default.htm

[3] IMDRF UDI Guidance: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf

[4] Regulation (EU) 2017/745 of 5 April 2017, Articles 27, 28 and 29: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG&toc=OJ:L:2017:117:TOC

[5] Regulation (EU) 2017/746 of 5 April 2017, Articles 24, 25 and 26: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746

[6] TGA – Medical device regulatory reforms: https://www.tga.gov.au/medical-device-regulatory-reforms

This Policy Paper on UDI reflects the joint position of the Australian peak industry bodies that collectively represent the majority of companies marketing medical devices in Australia (hereafter referred to as Industry):

- Medical Technology Association of Australia (MTAA)
- IVD Australia
- Australian Dental Industry Association (ADIA)
- AusBiotech, Australia's Biotechnology Organisation

Industry recommends that the following fundamental principles should be adhered to when implementing the UDI in Australia:

1. Adoption of a **globally harmonized UDI system**, in accordance with the IMDRF UDI guidance IMDRF/UDI WG/N7FINAL:2013;
2. Adoption of rules and policies that **align with international coding standards** of UDI issuing agencies designated in the EU and accredited in the U.S. - Automatic Identification and Data Capture (AIDC) such as linear or matrix bar code, smart cards, biometrics and Radio Frequency Identification (RFID); and Human Readable Interpretation (HRI);
3. Establishment of an Australian UDI database (AusUDID) **owned and managed by the TGA;** the best practice is for regulatory agencies to build their own UDID database. The AusUDID should allow sponsors to update information for their own products free of charge, and should be accessed by the general public free of charge.

In addition to the above principles, the Industry supports the recommendations of the Global Medical Technology Alliance (GMTA) in its January 2018 White Paper *Unique Device Identification (UDI): Insights and benefits from a single UDI System in the international arena*.[7]

In the next sections we provide further details explaining Industry's position.

[7]GMTA White Paper - UDI:
http://www.globalmedicaltechnologyalliance.org/papers/GMTA%20UDI%20White%20Paper.pdf

2. Globally harmonized UDI system

Most medical devices sold in Australia are imported from the U.S., Europe or Asia. Adopting a globally harmonized UDI system in accordance with the IMDRF UDI Guidance is essential to avoid unnecessary errors, duplication and costs within the healthcare supply chain.

The Australian UDI system would need to incorporate the same three parts as the global UDI system described in the IMDRF UDI Guidance:

1. The adoption of globally accepted UDIs - developed according to international standards ISO/IEC 15459-2[8], ISO/IEC 15459-4[9] and ISO 15459-6[10];
2. The application of the UDI on the label
3. The submission of appropriate information to the Australian UDI database (AusUDID)

The UDI implementation will need to be done in the context of the Australian medical device regulations and to leverage as much as possible the existing TGA systems and databases - the ARTG (Australian Register of Therapeutic Goods), SARA (System for Australian Recall Actions), IRIS (Medical Device Incident Reporting & Investigation Scheme) and DAEN (Database of Adverse Event Notifications). TGA systems and databases should be upgraded as needed to enhance effectiveness and efficiency of managing information about medical devices, for example by enabling linkage and interoperability between them.

The typical journey of a medical device within the supply chain might result in information about it being captured in various systems and platforms:

1) Manufacturing including labelling – this activity can take place in Australia or overseas; devices manufactured overseas enter the country with product identification already affixed on the device, packaging and Instructions for Use (IFUs)
2) TGA ARTG – inclusion denotes that the medical device can be legally marketed in Australia
3) Healthcare organizations purchasing systems and warehousing databases
4) Healthcare facilities sterilization and refurbishing systems and processes – for multi-use surgical tools and refurbished medical equipment
5) Patient's My Health Record (in the future) – for high risk implanted devices
6) Clinical quality registries – for high risk implanted devices such as joint replacements[11]
7) TGA IRIS – if the device has caused or may have contributed to an adverse event
8) TGA SARA – if the device is being recalled
9) TGA DAEN – if the device is the subject of an adverse event notification

[8] ISO/IEC 15459-2:2015 Information technology – Automatic identification and data capture techniques – Unique identification – Part 2: Registration procedures https://www.iso.org/standard/54780.html
[9] ISO/IEC 15459-4:2014 Information technology – Automatic identification and data capture techniques – Unique identification – Part 4: Individual products and product packages https://www.iso.org/standard/54782.html
[10] ISO/IEC 15459-6:2014 Information technology – Automatic identification and data capture techniques – Unique identification – Part 6: Groupings https://www.iso.org/standard/54786.html
[11]Australian Orthopaedic Association National Joint Replacement Registry https://aoanjrr.sahmri.com/home

Throughout its lifecycle, a medical device needs to be unequivocally identified to avoid confusion and unnecessary duplicative work to determine and communicate its exact, correct identity and status. The UDI is the device portable information achieving this objective.

Hereafter is an example that highlights efficiency gains that can be made by implementing a globally harmonized UDI system and in particular aligning the ARTG with the AusUDID.

Currently, a separate ARTG entry is required for every kind of medical device. Medical devices are of the same kind if they:

(a) have the same sponsor; and
(b) have the same manufacturer; and
(c) have the same GMDN code; and
(d) have the same risk classification; and
(e) have the same unique product identifier - for Class III, AIMD and Class 4 IVD only;

The unique product identifier is the product name or model number assigned by the manufacturer. The catalogue numbers of variants of the same model designation are equivalent to the Device Identifier (DI) portion of the UDI (see example in Figure 1).

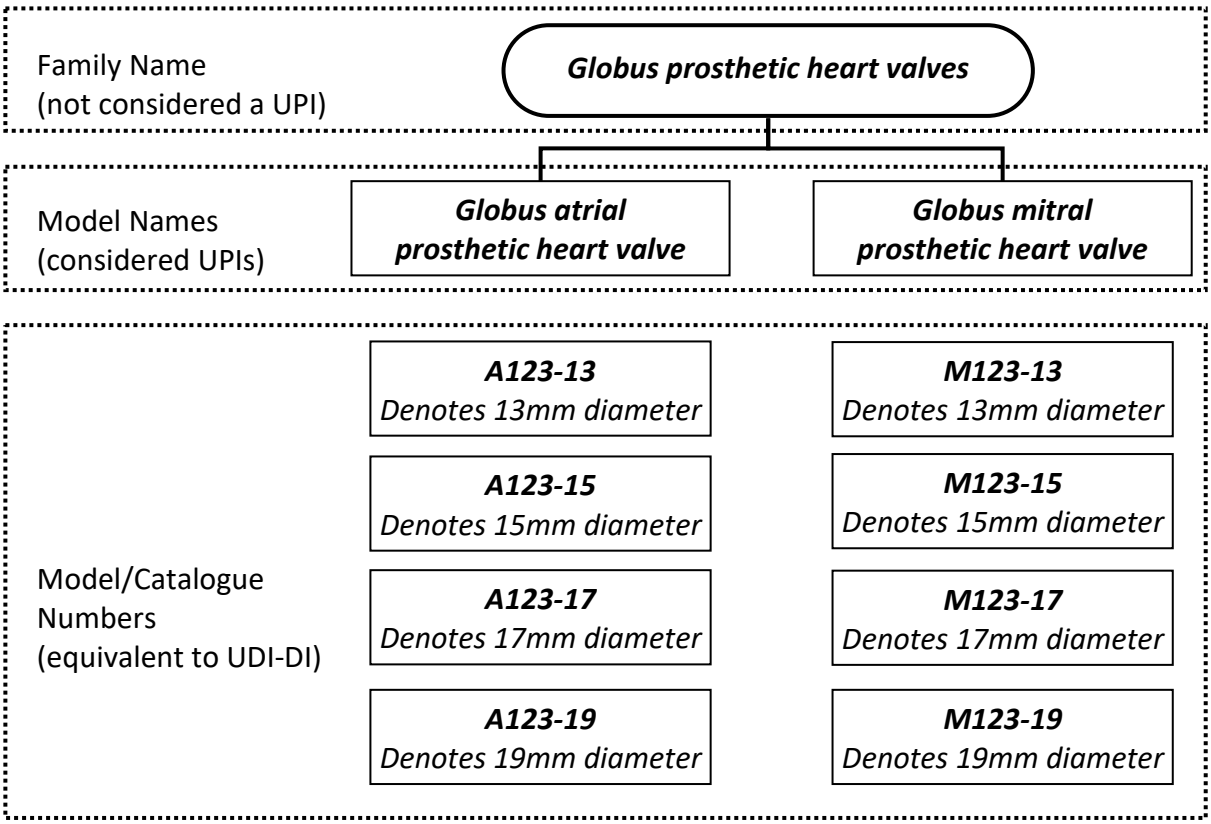

Figure 1: Example of family of prosthetic heart valves (from TGA ARGMD, V1.1 May 2011)

The current rules for ARTG inclusion have two unintended consequences that could be addressed by implementing a UDI system alongside the ARTG:

1) Inadequate traceability - real or perceived - to individual product names or model numbers for low and moderate risk devices - Class I, Class I^{s,m}, Class IIa and Class IIb non-IVD; and Class 1, 2 and 3 IVD, because only kinds of devices are entered in the ARTG;

2) Inability to enter Class III and AIMD devices and Class 4 IVD belonging to the same product family in the same ARTG entry, as separate ARTG entries are being used as surrogate traceability to individual product names or model numbers. Having to maintain multiple separate ARTG entries for products that typically share over 75-80% of the technical documentation results in administrative overheads without any added benefit to patient safety. (In the EU, high risk medical devices belonging to the same product family can be included in one EC Design Examination Certificate listing all individual product names or model numbers belonging to the product family.)

An AusUDID containing the core UDID data elements in accordance with section 9.2 of the IMDRF UDI Guidance, that is owned and managed by the TGA, would be able to "fill the traceability gap" for low and moderate risk devices - issue 1) above - and interface with the ARTG to ensure full traceability for all medical devices placed on the market in Australia.

The core AusUDID data in Table 1 contains both mandatory and non-mandatory fields. Certain core UDID data elements are already captured in the ARTG and should be easily transferable in the AusUDID without duplicative data entry. Certain core ARTG data have a one-to-many relationship to certain AusUDID data, for example ARTG ID (#1 in Core ARTG Data column) to License/ marketing authorisation (#22 in Core AusUDID Data column); and UPI (#9 in Core ARTG Data column) to UPI (#26 added in the Core AusUDID Data column) – see Table 1.

In 2015 the TGA noted that: "Options for amending the way a kind of medical device is included in the ARTG to improve identification and traceability have been overtaken by development of an international system of Unique Device Identifiers (UDIs). This new global approach is to be rolled out by the US Food and Drug Administration over the next seven years, with corresponding UDI provisions under development in Europe. In providing unique identifiers for medical devices this system will improve device traceability as well as providing for better identification of devices by health care professionals and consumers. As the UDI system is being rolled out internationally, there is scope for Australia to harmonize and gain the advantages and efficiencies of this approach, avoiding the duplication and cost of implementing separate product identification measures."[12]

[12] TGA reforms: A blueprint for TGA's future: Progress report as at 31 December 2014, dated 8 April 2015 https://www.tga.gov.au/book/expected-benefits-reforms-3

Table 1: Core ARTG data, globally-aligned core AusUDID data and commonality between the two data sets

Core ARTG Data
1. ARTG ID
2. ARTG Name
3. Sponsor Name
4. Sponsor Address
5. Manufacturer Name
6. Manufacturer Address
7. GMDN preferred code and term
8. Kind of medical devices
9. Unique Product Identifier (UPI) – uniquely identify device and its variants; applicable to high risk devices only
10. Variant information (diameter, gauge, shape, number of strands for sutures, volume) – high risk devices only
11. Device risk class
12. ARTG effective date

Core AusUDID Data
1. For every device packaging level: UDI-DI - GS1 GTIN, HIBC-LIC or ISBT-128 PPIC Quantity per package configuration Additional device identifier(s) – GS1, HIBC or ISBT-128
2. The Unit of Use (UoU) UDI-DI associating the use of a device with a patient; units of measure/issue
3. Manufacturer Name
4. Manufacturer Address
5. Manufacturer customer service contact info - multiple
6. Authorised Representative Name, i.e., Australian Sponsor Name
7. Authorised Representative contact info, i.e., Australian Sponsor contact info
8. GMDN preferred code and term
9. Brand Name
10. Software as Medical Device (SaMD) version
11. Device model or version
12. Reference and/or catalogue number
13. How the device is controlled – serial, lot/batch number, and/or expiration date or manufacturing date or SW version or SW release date or ISBT-128
14. Clinical size – volume, length, gauge, diameter
15. Additional product description
16. Storage conditions - t° range, RH% range, pressure range, refrigerate, avoid direct sunlight
17. Handling conditions - t° range, RH% range, pressure range, refrigerate, avoid direct sunlight
18. Labelled as Single Use
19. Packaged sterile
20. Need for sterilization before use
21. Restricted number of reuses
22. License/ marketing authorisation/ registration number, i.e., ARTG ID in Australia
23. URL for additional info – eIFU
24. Critical warnings/ contraindications – latex/DEHP/MRI
25. Date of discontinuance/ withdrawal from market
26. Unique Product Identifier (UPI) – specific to Australia

Common data:

Core ARTG Data ⇔	Core AusUDID Data
#1	#22
#3	#6
#4	#7
#5	#3
#6	#4
#7	#8
#9	#1, #11
#10	#14

3. UDI Issuing Agencies

The European Commission and the U.S. FDA have designated/ accredited three UDI issuing agencies to date[13,14]:

- GS1
- HIBCC (Health Industry Business Communications Council)
- ICCBBA (International Council for Commonality in Blood Banking Automation)

Official designation/ accreditation of UDI issuing agencies ensures that the systems for the issuance of UDIs that are operated by designated/ accredited issuing agencies conform to certain international standards.

Industry's position is that TGA should also accredit UDI issuing agencies locally. Australia should recognize and accept UDIs issued by all EU-designated/ U.S.-accredited UDI issuing agencies - GS1 GTIN, HIBC and ISBT-PPIC - without favouring or endorsing any single one in particular. This will enable a level playing field and ensure that the UDI systems that are implemented in Australia will not impede global trade of therapeutic goods.

Healthcare facilities and other purchasing organizations will need to implement systems capable of 'reading' UDIs in any of the three acceptable formats.

4. Australian UDI Database (AusUDID)

Establishment and maintenance of a UDI Database according to the IMDRF UDI Guidance is an important element of a UDI system. Both in the EU and the U.S. the UDI databases are owned and administered by the regulatory authorities, and essential UDI database information is available to the public free of charge.

The U.S. FDA set up the Global Unique Device Identification Database (GUDID), which is a database administered by the FDA that serves as a reference catalogue for every device with an identifier. The GUDID contains only the device identifier (DI), which serves as the primary key to obtain device information in the database. Production Identifiers (PIs) are not submitted to or stored in the GUDID, but the GUDID contains PI flags to indicate which PI attributes are on the device label. [15]

[13] Regulation (EU) 2017/745 of 5 April 2017, Article 12, Item 12: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745

[14] FDA UDI Issuing Agencies: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm

[15] FDA Global UDI Database (GUDID): https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm

Device labellers (medical device sponsors and/or manufacturers) require a GUDID account to submit device identification information. Importantly, the public can access published GUDID information free of charge (not requiring a GUDID account) through the public portal AccessGUDID[16].

Likewise, the EU Medical Device Regulation states in Article 28 that the Commission "shall set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Annex VI" and "the core data elements to be provided to the UDI database, referred to in Part B of Annex VI, shall be accessible to the public free of charge". (Part B of Annex VI lists the core UDI database data elements.)

Industry's position is that a similar model should be adopted in Australia, whereby the TGA sets up and manages the AusUDID and essential information is made publicly available free of charge. The AusUDID will need to accept UDIs issued by all and any of the EU-designated/ U.S.-accredited UDI issuing agencies - GS1 GTIN, HIBC and ISBT-PPIC.

Industry recommends that the other TGA essential databases – ARTG, SARA, IRIS and DAEN – should be upgraded to easily interface with the AusUDID and thus deliver the benefits they were intended to, i.e., optimum traceability and post-market safety monitoring.

5. Further considerations for implementation of an UDI System in Australia

The UDI rules stipulate that the UDI labelling must be readable to both machines and humans. Machine-readable Automatic Identification and Data Capture (AIDC) technologies include barcodes (linear) and data matrices (2-D), smart cards, biometrics and radio frequency identification (RFID). For example, the U.S. FDA requires that the UDI string (i.e. the entire UDI string as it would be on the barcode) be placed in human readable form below/alongside the barcode.

Human readable strings can get very long and difficult to include on labels of small devices where space is very limited. Actually, the UDI string was intended to be machine readable and not by humans. In our opinion, mandating human readable UDI strings on labels defeats the purpose of using barcodes and data matrices. Mandatory human readable device labelling is covered in regulations (Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1 - Essential Principles, Section 13 Information to be provided with medical devices)[17] and does not need to be duplicated by UDI strings.

MTAA and IVDA are members of the Global Medical Technology Alliance (GMTA). In January 2018 the GMTA published the White Paper *Unique Device Identification (UDI): Insights and Benefits from a Single UDI System in the International Arena*. Industry fully supports the GMTA findings and recommendations.

[16] FDA, AccessGUDID: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm444831.htm

[17] Therapeutic Goods (Medical Devices) Regulations 2002: https://www.legislation.gov.au/Series/F2002B00237

The GMTA paper draws on lessons learned from recent experience with UDI implementation in the U.S. and makes the following 10 recommendations:

1) UDI rules should be adopted in a globally harmonized manner.
2) UDI rules should offer a phased in approach with implementation based on product risk classification. The implementation period should begin no less than two years from issuance of the regulation and when the UDI database is available.
3) UDI rules and policies should rely on international standards and globally accredited UDI issuing agencies, in addition to the IMDRF UDI Guidance, and consider the evolution of UDI technology.
4) Manufacturers should be permitted to submit information to databases using standards-based submission options to account for their variation in size and capabilities, such as the use of web interfaces or HL7 formats. Globally standardized core data elements should become the common denominator for any national implementation.
5) Regulators should provide assistance when implementing a new UDI system, such as setting up a help desk, providing training opportunities, and issuing guidance documents.
6) UDI rules should provide the regulator with an efficient and expedient mechanism to grant exceptions, exemptions, alternatives and extensions that may exist for specific product areas or for specific manufacturers.
7) UDI rules should exempt all devices manufactured or labelled prior to the UDI rule effective date, including those that are held on a consignment basis.
8) Regulators should understand the implementation variations that occur between manufacturers with respect to use of device identifiers and maintain flexibility to account for a manufacturer's specific needs by staying within the established framework of the globally accredited UDI issuing agencies.
9) Regulators should drive global convergence for the use of new product identifiers.
10) Implementation timelines related to UDI database changes must account for industry's needs to update internal systems and processes.

In addition, the GMTA paper also raises implementation issues not covered in the IMDRF UDI Guidance and makes further recommendations on each of those:

1) Utilization of a phased-in and risk-based approach

   Recommendation: UDI rules should offer a phased-in and risk-based implementation approach. The initial implementation period should begin no less than two years for the highest risk devices.

   Australian industry recommends that UDI implementation timelines in Australia are synchronised, with an appropriate time lag, with those in the EU.

2) Reliance on standards and globally accredited issuing agencies

   Recommendation: In addition to the IMDRF Guidance, UDI rules and policies should be based on international standards and globally accredited UDI issuing agencies, including those mentioned above, and existing organizations that support healthcare supply chains. In addition, regulators should consider the evolution of UDI technology by adopting technology neutral regulations.

3) Access to information and submission methods

   Recommendation: Manufacturers should be permitted to submit information to databases using standards-based submission options to account for their variation in size and capabilities, such as the use of web interfaces, HL7 formats or GDSN.

4) Providing assistance to industry: help desk, training and guidance

   Recommendation: Regulators should provide assistance when implementing a new UDI system, including at least the following:

   a) Establish a Help Desk that manufacturers can access easily throughout the implementation period of a UDI rule, and make such responses available to the public.
   b) Offer frequent training opportunities for manufacturers prior to and during the system's implementation period, including webinars with question and answer sessions and in-person training events.
   c) Issue guidance documents in a timely manner that explain how the agency interprets complex and nuanced portions of the UDI rule, and update the guidance documents as needed.

5) Exceptions, exemptions, alternatives and extensions

   Recommendation: UDI rules should provide the regulator with an efficient and expedient mechanism to grant exceptions, exemptions, alternatives and extensions that may exist for specific product areas or for specific manufacturers.

Lastly, the GMTA paper makes the following recommendations based on information learned while implementing the UDI Rule in the U.S.

1) Initial implementation timelines should be 2 years or more

   Recommendation: An initial implementation timeline of at least two years will better permit a smooth transition for the first set of devices subject to the rule. Doing so will provide industry— and the regulatory agency responsible for UDI implementation— sufficient time to address initial implementation concerns prior to the first effective date.

   Australian industry recommends that UDI implementation timelines in Australia are synchronised, with an appropriate time lag, with those in the EU.

2) Clarify date of manufacture when defining production identifier

   Recommendation: The device's date of manufacture should not be a required production identifier when other means of production identification appear on the device label.

3) Small medical device exemption

   Recommendation: UDI rules should provide for a general exemption for small medical devices.

4) UDI Rules should exempt all devices manufactured or labelled prior to the UDI Rule effective date

   Recommendation: UDI rules should exempt all devices manufactured or labelled prior to the UDI rule effective date, including those that are held on a consignment basis.

5) Drive global convergence for use of new product identifiers

   Recommendation: It is important to understand the implementation variations that occur between manufacturers with respect to use of device identifiers and maintain flexibility to account for a manufacturer's specific needs by staying within the established framework of the globally accredited UDI issuing agencies.

6) Changes to databases

   Recommendation: Changes to a UDI database should be minimized as much as possible. Implementation timelines related to a UDI database change must account for industry to update internal systems and processes. This holds true even for what may appear to be a simple change. Providing adequate time to implement database changes will ensure the data flow remains accurate and timely.

   In addition, system downtime should be published in advance when possible, and allowances made for submissions when a system's downtime may have interfered with the applicable compliance date.