

Compilation of Eucomed UDI Articles

For use by Eucomed ETF Members Only

What's New? 10th June 2011

The impact of Unique Device Identification on French businesses, the economy and the regulatory environment

(www.eucomed.org/newsletternews/115/104/The-impact-of-Unique-Device-Identification-on-French-businesses-the-economy-and-the-regulatory-environment/)

What's New? 6th May 2011

Eucomed releases two new documents to explain Unique Device Identification

(www.eucomed.org/newsletternews/82/104/Eucomed-releases-two-new-documents-to-explain-Unique-Device-Identification/)

(Links to:)

Technical Information Sheet - Unique Device Identification (UDI)

(www.eucomed.org/uploads/_key_themes/Regulatory/110405_technical_sheet_UDI.pdf)

General Information Sheet - What is UDI and why it is important to Healthcare

(www.eucomed.org/uploads/_key_themes/Regulatory/110405_general_information_sheet_UDI.pdf)

What's New? 8th April 2011

UDI, GS1, GTIN, GHTF, ETF, EHR, ISMP...

What does it mean to me and to you?

(www.eucomed.org/newsletternews/49/104/UDI-GS1-GTIN-GHTF-ETF-EHR-ISMP-What-does-it-mean-to-me-and-to-you/)

(www.eucomed.org/blog/76/59/UDI-GS1-GTIN-GHTF-ETF-EHR-ISMP-What-does-it-mean-to-me-and-to-you/)

(<http://eucomed.blogactiv.eu/2011/04/01/udi-gs1-gtin-ghtf-etf-ehr-ismp-what-does-it-mean-to-me-and-to-you/>)

Newsroom 22nd July 2009

Unique Device Identification (UDI): Getting ready

(www.eucomed.org/newsroom/42/104/Unique-Device-Identification-UDI-Getting-ready/)

(Link to:)

Risk-based implementation of Unique Device Identification (UDI)

([www.eucomed.org/uploads/Press%20Releases/Risk-based%20implementation%20of%20Unique%20Device%20Identification%20\(UDI\).pdf](http://www.eucomed.org/uploads/Press%20Releases/Risk-based%20implementation%20of%20Unique%20Device%20Identification%20(UDI).pdf))

The impact of Unique Device Identification on French businesses, the economy and the regulatory environment

On 31 May 2011, the French national Medical Technology industry association SNITEM organised a one-day seminar on Unique Device Identification (UDI) and the traceability of medical devices. The aim was to inform its members on the impact of UDI on their businesses and on the economic and regulatory environment. The event was attended by over 70 people.

UDI is set to have a significant impact on the industry and the cost of doing business. In line with a global initiative by regulators to bring increased safety through increased traceability of devices, the European Commission has signalled its intention to propose legislation in 2012 requiring all manufacturers to implement UDI potentially from as early as 2014 onwards.

While the requirement may bring some benefits to manufacturers in terms of more efficient business processes through improved monitoring of usage and costs, manufacturers in general will face significant costs in altering production and labelling lines. Healthcare providers will need to be suitably equipped and their staff trained. However, the legislation will be directed only at the manufacturer and thus it is vital that national and regional authorities take the necessary steps to ensure that their healthcare systems are able to respond.

Achieving this will require a high level of awareness and commitment among all stakeholders in the healthcare system (from manufacturer to hospital management to healthcare professional and patient). This can only be achieved if the authorities are also fully committed. At Eucomed, the topic of UDI is discussed by the e-business and supply chain task force (ETF) which particularly focuses on the increasing needs, developments, policy and implementation of UDI.

The European Commission defines UDI as a unique number pertaining to a medical device that enables the identification of different types of devices, and the access to useful and relevant information stored in a UDI database. Due to the UDI's specificity, it can make traceability of devices more efficient, allow easier recall of devices, fight against counterfeiting, and improve patient safety.

The day was composed of various sessions led by experts:

Standards in 2011: Development of GS1 Standards in France and in Europe

Valérie Marchand - GS1 France

UDI: an international reality (GHTF, US FDA, Europe)

Rodolphe Muñoz - European Commission, Unit B2 - Cosmetics & Medical Devices Health & Consumers Directorate-General

UDI and regulatory: point of view from French Health Products Safety Agency (AFSSAPS)

Nicolas Thevenet - AFSSAPS, Evaluation of medical devices Directorate

Reality of UDI in a healthcare setting: needs and expectations from pharmacists today and in the future

Olivier Sellal – Hospital of Nantes, Hospital Pharmacist

Codification: from creation to use in hospitals and other healthcare settings: stakes and perspectives

Agnès Vabois - ACL, Project Director & Patrick Oscar - ACL, Director General

UDI from the point of view of an international company: constraints, interoperability of exchanges and productivity gains expected

Jean-Pierre Trevisani - TERUMO European Marketing Information Manager

Participants had the opportunity to ask questions and exchange points of view with the speakers during two insightful round table discussions.

For further information: www.snitem.fr

www.gs1.fr/gs1_fr/secteurs_d_activite__1/sante

Eucomed releases two new documents to explain Unique Device Identification

Unique Device Identification (UDI) is a requirement for medical devices to carry (on the labelling and in some cases directly on the device) a unique machine-readable identifier (e.g. bar code) allowing the unambiguous identification of the medical device. This will undoubtedly result in important benefits for all healthcare partners such as:

- **Improved patient safety:** making it easier to trace devices and record which patient they have been used on;
- **Better regulatory control:** Regulators will be able to more readily, accurately and efficiently, identify devices if there is a recall resulting from an adverse device event;
- **More efficient business processes:** improved monitoring of usage and costs.

However, like so many initiatives, it will also involve initial up front expenditure particularly by industry as well as by the end users.

As with any new development, there are a number of concerns that must be addressed as soon as possible and at Eucomed, the E-Business and Supply Chain Task Force (ETF), has been focusing on the increasing needs, developments, policy and implementation of UDI.

In order to raise awareness on UDI, the Task Force has released two new documents: a “*Technical Information Sheet*” and a “*General Information Sheet*”. Both documents explain the benefits and opportunities of UDI, as well as highlighting a number of concerns related to the impact of UDI on medical technology companies. The next phase will be to focus on information sheets for databases (UDID) as this may be of greater concern to industry.

Last month, Mike Kreuzer, Chairman of the Eucomed ETF Task Force, wrote a blogpost (www.eucomed.org/blog/76/59/UDI-GS1-GTIN-GHTF-ETF-EHR-ISMP-What-does-it-mean-to-me-and-to-you/) where he explained that industry had provided bar coded products to a hospital which did not have the knowledge nor the equipment to use them. This is another concern for the Eucomed ETF Task Force and illustrates why these new documents are important for all current and future users of UDI.

The Global Harmonization Task Force (GHTF) adhoc working group on UDI is currently preparing guidance for industry and regulators. Eucomed has been involved with this group and is highlighting the need for industry to be prepared for UDI legislation, especially with the recast of the Medical Devices Directive and because legislation is already in place in other countries.

UDI is a ‘key’ to improved process and therefore greater safety and reduced costs in healthcare. Without UDI these process will be difficult or impossible to achieve electronically and extremely cumbersome to handle manually, with further risk of inaccuracy due to manual intervention in data entry. For this reason UDI deserves the support of all concerned: industry, healthcare providers and the authorities.

- Technical Information Sheet – Unique Device Identification (www.eucomed.org/uploads/_key_themes/Regulatory/110405_technical_sheet_UDI.pdf)
- General Information Sheet – What is UDI and why it is important for Healthcare (www.eucomed.org/uploads/_key_themes/Regulatory/110405_general_information_sheet_UDI.pdf)
- UDI,GS1, GTIN, GHTF, ETF, EHR, ISMP... What does it mean to me and to you? (www.eucomed.org/blog/76/59/UDI-GS1-GTIN-GHTF-ETF-EHR-ISMP-What-does-it-mean-to-me-and-to-you/)

For more information, please contact Merlin Rietschel (merlin.rietschel@eucomed.org)

Unique Device Identification (UDI)

UDI can be defined as a requirement for medical devices to carry (on its labelling and in some cases directly on the device) a unique machine-readable identifier. This has three distinct elements:

1. An ISO compliant (e.g. GS1, HIBC...) Unique Device Identifier (static data) plus production identifiers (dynamic data) as appropriate
2. The application of the UDI on the packaging (and specific devices) in a machine-readable format (bar code, RFID tag).
3. The capture of appropriate information, to identify the device, to/from a regulated database (UDID)

The UDI will contain static data to identify the device and this will be the access key to the UDID. There will be a requirement to identify a limited number of globally accepted data elements (attributes) but national/regional additions should be avoided. There should be no intention of storing dynamic data (e.g. production identifiers for traceability purposes) in the UDID. It should also be noted that in UDI the word 'unique' does not imply device serialisation. This is an additional identifier which will be required for specific devices.

Bar codes have been widely used for many years, for logistical purposes on shipping containers. Putting a unique identifier on the actual device or on other levels of packaging is a revolutionary step and would have many benefits:

- **Improved patient safety:** making it easier to trace devices and record which patient they have been used on;
- **Better regulatory control:** Regulators will be able to more readily, accurately and efficiently, identify devices if there is a recall resulting from an adverse device event;
- **More efficient business processes:** improved monitoring of usage and costs.

It is only relatively recently that the authorities, particularly in Europe, have begun to address UDI & UDID but today there is a cultural and a legislative will to move this forward. The US Food and Drug Administration (FDA) are preparing legislation, which is likely to be announced in mid 2011. The FDA participates together with other regional authorities in a GHTF (Global Harmonization Task Force) UDI ad hoc working group, lead by the EU Commission. This group is working to harmonise requirements for UDI/UDID globally. The advent of legislation in the world's largest market for devices will have a significant influence on the global development of a UDI/UDID system and the EU Commission will include a requirement for UDI in the forthcoming Revision (Recast) of the Medical Devices Directive where a final proposal is expected in early 2012. An EU Commission working group with the Member States has been established to progress this.

The devices industry works closely with GS1, a not for profit organisation which is the issuing agency for the majority of bar codes used globally, across many industry sectors. GS1 Healthcare has set up a global network of device industry and healthcare professionals to develop and enhance specific standards for UDI. This approach is supported by the GHTF, the FDA, the EU Commission as well as authorities in the UK, Australia, Japan, India and an increasing number of other countries.

UDI will undoubtedly bring many benefits and it will also reduce healthcare costs by improving efficiency. However, like so many cost saving initiatives, it will also involve initial up front expenditure from industry through to the end user. Industry therefore has a number of concerns:

- Manufacturers will face significant costs in altering production and labelling lines and healthcare providers will need to be suitably equipped and their staff trained. However the legislation will be directed only at the manufacturer and it is vital that national and regional authorities take the necessary steps to ensure that their healthcare systems are able to respond. Achieving this will require a high level of awareness and commitment among all stakeholders in the healthcare system (from manufacturer to hospital management to healthcare professional and patient). This can only be achieved if the authorities are also fully committed.
- Local (regional or country) deviation would have a negative impact on supply chain efficiency and would generate associated costs and risks. Several instances of this have already surfaced and it is essential that Member State administrations are vigilant to ensure that this trend does not proliferate.
- It is important for all concerned that such a wide ranging requirement as UDI is introduced in a pragmatic manner with the higher risk devices being the first to be subject to mandatory marking and that thereafter a step-wise approach to implementation is adopted.

(Published: April 2011)

What is UDI and why it is important for Healthcare

Bar codes have been used for many years in the retail industry and, for logistical purposes, on shipping containers used by manufacturers, including those making medical devices. Today there are revolutionary developments taking place worldwide, which will mean that unique identifiers (e.g. bar codes) will be required to be placed on medical devices. This will have many benefits:

- **Improved patient safety:** making it easier to trace devices and, where appropriate, record which patient they have been used on;
- **Better regulatory control:** more accurate identification of devices if there is a product recall;
- **More efficient business processes:** improved monitoring of usage and costs for both industry and healthcare providers.

This development is known as UDI (Unique Device Identification) which is a requirement for medical devices to carry (on the labelling and in some cases directly on the device) a unique machine-readable identifier. The UDI is a series of numeric or alphanumeric characters created through a global coding standard allowing the unambiguous identification of a specific medical device. It should also be noted that in UDI the word 'unique' does not imply device serialisation. Only certain devices will need to be identified individually rather than by their production lot/batch.

It is only relatively recently that the potential benefits of UDI have become apparent. Today, the authorities both in the USA and Europe are addressing UDI by creating legislation, which will require all medical device manufacturers to mark their products with a unique identifier. The EU will incorporate UDI in the revised Medical Device directives and the US FDA is preparing similar legislation. Both participate with other regional authorities in a group which is working to harmonise requirements for UDI globally. By 2018 all devices will be required to have a unique identifier, although in some countries it is already a regulated requirement, which industry should not overlook.

The devices industry works closely with GS1, a not-for-profit organisation which is the issuing agency for the majority of bar codes used globally, across all industry sectors. GS1 Healthcare has set up a global network of device industry and healthcare professionals to develop specific standards for UDI. This approach is supported by the FDA, the EU Commission as well as authorities in the UK, Australia, Japan, India and an increasing number of other countries.

UDI will undoubtedly bring many benefits and it will also reduce healthcare costs by improving efficiency. However, like so many cost saving initiatives, it will also involve initial up front expenditure particularly by industry. As with any new revolutionary development, there are a number of concerns:

- **Health Systems need to invest and upgrade:** It is vital that authorities worldwide take the necessary steps to ensure that their systems are able to respond. The legislation will be directed only at the manufacturer who will face significant costs in altering production and labelling lines, creating extensive databases (UDID) and support mechanisms. If there is no equivalent high level of awareness and commitment to training and updating equipment on the part of healthcare providers, then the potential benefits of UDI, not to mention the significant investment by industry, will be lost.
- **One Globally coherent UDI:** A product should be identifiable anywhere in the world. However authorities must not 'jump the gun'. Enthusiasm to implement UDI and set up databases (UDID) is commendable but it should only be done with full regard to the developing legislation and to global standards. Local (regional or country) deviation can have a negative impact on supply chain security and efficiency, generates associated unnecessary costs and can create unforeseen risks.
- **Pragmatic Approach:** To take account of the scale of the project, (nearly 500,000 types of products from many thousands of manufacturers, worldwide) it is important that such a wide ranging requirement as UDI is introduced in a pragmatic manner which requires full co-operation between all parties involved.

UDI is a 'key' to improved process and therefore greater safety and reduced costs in healthcare. Without UDI these process will be difficult or impossible to achieve electronically and extremely cumbersome to handle manually, with further risk of inaccuracy due to manual intervention in data entry. For this reason UDI deserves the support of all concerned: industry, healthcare providers and the authorities.

(Published: April 2011)

UDI, GS1, GTIN, GHTF, ETF, EHR, ISMP... What does it mean to me and to you?

Having been involved with the medical devices industry for many years, I've seen how the industry has evolved using innovative solutions and has constantly embraced technological developments. Recently however I had a friend on the receiving end of this technology and I hope you find his 'patient case report' below of interest - do note he also works in the medtech industry hence his knowledge on this subject:

"Firstly I'm thinking of starting an organisation named OHIHA. No, it's not an expression from a cowboy western movie but 'Oh How I Hate Acronyms', mainly because I can never remember them! This is about patient safety and healthcare technology and with my advancing years the 'old trusted ticker' [heart] has been coming under a bit of strain recently and a number of investigations were recommended by my GP (General Practitioner), including an angiogram. Upon arrival at the angiography department I was provided with a 'bar coded' patient wristband (not another acronym; UPI - Unique Patient Identification?), at which point I started to think about 'patient safety'. Half an hour before the procedure all the 'risks' were clearly explained; stroke, heart attack, excessive bleeding... Suddenly there was a power failure and the emergency generators started immediately, but only for lighting and other essential equipment, not the refrigerators containing drugs? This wasn't mentioned as one of the 'risks'. One nurse very kindly asked the patients if they had any spare money for the electricity meter, as the power failure might have been caused by funding cutbacks. Twenty minutes later the electricity supply was restored (without further patient funding) and everything was ready. I was surrounded with many bar coded medical devices, bar coded drugs, bar coded contrast media and I had my UPI. Patient safety (my wellbeing) was at the forefront of my thoughts again but then I discovered to my surprise (even horror) that another 'risk' had been completely overlooked, there were no bar code scanners in the department and none of the staff knew anything about bar coding. Fortunately the patient wristband had 'back-up' human readable information on it and I was 'identified, verified and authenticated' and the procedure went ahead (with no clinical complications I'm pleased to say).

Lying in 'recovery' I could see animated patterns, in my peripheral vision (a side effect of the contrast media), which reminded me about bar codes again. Suddenly, alarm bells started to ring. No, they weren't in my head but there was a fire in another wing of the hospital, which had to be evacuated. During the next two hours I continued to see and think about 'twinkly patterns'; most were 'linear' with a gradual change to 'data matrix', but after drinking lots of fluid (tea and water) the patterns gradually disappeared, which left me with the following thoughts; industry provides bar codes on medical devices and pharmaceuticals, regulators are regulating them (FDA, EU Commission...), working groups are working on them (GHTF...), standards organisations are standardising them (ISO, GS1...), trade associations are supporting them (Eucomed ETF⁽¹⁾...), some countries are even localising them (but that's another story and another major concern) and hospitals are printing them on patient wristbands but, when will all hospitals be properly funded and equipped to be able to use them effectively?

*I then thought of how many other patients are faced with the same situation (and potential risks), not just in the UK but worldwide and I related this experience to Mark Neuenschwander⁽²⁾, a world leading authority on bar coding and evangelist for patient safety. He said that it reminded him of a chapter from the children's classic *The Owl at Home* entitled "Tear-Water Tea". Owl decides to make tear-water tea. So he puts a teapot on his lap and thinks of very sad things. The resulting tears start to fill the pot. He thinks of books that will never be read, pencils that are too short to use and left over mashed potatoes that will never be eaten. Mark then wondered about bar codes that will never be scanned and added, "that would have filled Owl's pot to overflowing". Rather poignant as I was having to drink lots of fluids, including tea, to clear the 'twinkly patterns' but in reality we need to use them."*

There are so many benefits to UDI (Unique Device Identification) using bar codes containing GTINs (Global Trade Item Numbers) based on Global Standards (GS1); not just patient safety but supply chain efficiency, product traceability, EHR (Electronic Healthcare Records), anti-counterfeiting, reimbursement, cross border trading, authentication, eCommerce, etc.

Now, with a new European Directive 'patient rights on cross border healthcare', does this strengthen the need for EU wide standardisation for UDI using Global Standards (not local standards)? Just consider the following from the Directive; The Commission shall adopt measures to facilitate the correct identification of medicinal products or medical devices. Is this another step towards EU (European Union) wide standardised UDI? In today's healthcare environment, Patient Safety has to be at the forefront of everyone's thoughts and bar coding [UDI] is a technology that is proven and will help with this global initiative, as long as global standards are used.

I just hope that bar coding doesn't remain in everyone's peripheral vision but comes sharply into focus.

Mike Kreuzer Chairman of the Eucomed Taskforce on E-Business and Supply Chain Management (ETF)

1. Eucomed ETF Task Force was established in June 2000 and in recent years has focused on the increasing needs, developments, policy and implementation of UDI. To read more go to: www.eucomed.org/newsroom/42/104/Unique-Device-Identification-UDI-Getting-ready/
2. On December 7th 2010 the Institute of Safe Medication Practitioners (ISMP) presented Mark Neuenschwander with their 10th Lifetime Achievement Award for his extraordinary contributions to medication safety.

Unique Device Identification (UDI): Getting ready

Brussels, 22 July 2009. Eucomed has today issued guidance on how UDI can be implemented in a practical way by using a risk-based approach.

Eucomed not only strongly advocates a global standardised approach with regard to UDI (Unique Device Identification), but also believes a risk-based approach is needed. To effectively implement UDI you need to evaluate the actual risk in respect of patient safety and also the risks associated with counterfeiting and reimbursement fraud. This is especially true if serialisation is considered as a requirement for specific classes or types of products.

Mike Kreuzer, chair of the Eucomed E-Business Task Force, said: *“UDI is moving up the MedTech industry agenda and it is vital that a step by step approach is adopted when it comes to implementation.”*

The guidance does not provide any technical details about how the UDI system should work globally as this is subject to ongoing activities of the adhoc Working Group of the Global Harmonization Task Force (GHTF). A more detailed document with practical guidance is to be elaborated once the final GHTF recommendations have been made public. Guidance details about traceability (track and trace) requirements of devices will also be provided at a later stage.

Usefull downloads:

- Risk-based implementation of Unique Device Identification (UDI)
([www.eucomed.org/uploads/Press%20Releases/Risk-based%20implementation%20of%20Unique%20Device%20Identification%20\(UDI\).pdf](http://www.eucomed.org/uploads/Press%20Releases/Risk-based%20implementation%20of%20Unique%20Device%20Identification%20(UDI).pdf))

About Eucomed

Eucomed is the Voice of the medical technology industry in Europe. Eucomed represents directly and indirectly 4500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Small and medium sized companies make up more than 80% of this sector. The European medical technology industry invests some €5.8 billion in R&D and employs near to 530,000 highly skilled workers. The mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology.

For more information, please contact Merlin Rietschel (merlin.rietschel@eucomed.org)

Risk-based implementation of Unique Device Identification (UDI)

Improving patient safety through product identification and traceability

Introduction:

The purpose of this paper is to provide basic guidance only on how UDI can be implemented practically by using a risk-based approach. The document does not provide any technical details about how the UDI system should work globally as this is subject to ongoing activities of the GHTF AHWG¹. A more detailed document with practical guidance is to be elaborated once the final GHTF recommendations have been made public. Guidance details about traceability (track and trace) requirements of devices will be provided at a later stage.

Reference is made in this document to; Class I, IIa, IIb & III devices, which are based upon the European Medical Devices Directive. Other countries have different classification systems such as the USA & Japan, where Class IIa & Class IIb have alternative classifications.

Executive summary:

In order to further promote patient safety, both the European Union and National Authorities have considered, and some even adopted, legislative requirements to improve product identification and traceability. This has been done through mechanisms such as bar coding.

The European Commission recently adopted a legislative proposal for a '*Counterfeiting Directive*'. This proposal includes a legal basis for serialisation of pharmaceuticals, potentially setting a precedent for medical devices. In the area of medical devices, the European Commission recently held a consultation on the issue of 'Unique Device Identification', or UDI, in the framework of the GHTF. This consultation was used to gather stakeholder input for a future legislative proposal in the field of medical devices.

Eucomed members have been looking into the issue of product identification and traceability and are implementing improved product identification systems. However, this is a gradual process and for cost-efficiency reasons cannot take place all at once. That's why Eucomed in the past has recommended the use of standardised product identification systems and has advocated a risk-based approach for traceability requirements.

Now that legislative activity in this area, at a National and European level is increasing, Eucomed wants to increase its pro-active approach, update its position and further increase its external policy influencing activities relating to UDI. This paper, prepared by the Eucomed e-Business and Supply Chain Task Force (ETF), may be used with government authorities and other external bodies. It has to be emphasised however that UDI (or any other technology for traceability) will only be effective in achieving the regulatory or public health benefits claimed if; distributors, hospitals and clinics have appropriate equipment to read UDI, store identifying information and allow timely and accurate data interrogation and exchange.

Key elements of Eucomed's position on UDI include:

- a standardised approach to product identification

Manufacturers should aim at having product identification (UDI) on their product packaging, unless this is technically or physically not possible. In order to improve the functioning of the single market, boost international trade in medical devices and improve patient safety in a cost-effective and efficient way, Eucomed strongly advocates a standardised approach with regard to UDI product identification based on global standards.

- a risk-based approach for traceability requirements

Eucomed is committed to improving patient safety through efficient traceability mechanisms. With regard to tracking and tracing, Eucomed believes a risk-based approach is needed to evaluate the actual risk to patient safety and the risks associated with counterfeiting and reimbursement fraud, especially if serialisation is considered as a requirement, for specific classes or types of products.

¹ Global Harmonization Task Force Ad Hoc Working Group

Technical background:

Auto-ID / Serialisation / Traceability

Several Auto-ID/ bar coding initiatives are currently being considered at European and National levels. Eucomed would welcome a standardised approach in this respect (e.g. the GS1 System of Global Standards), and its members are increasingly using and moving towards the use of linear and/or two dimensional (2-D data matrix) bar code symbologies for its industry's diversified portfolio of medical devices. With regard to the use of RFID (Radio Frequency IDentification), Eucomed recognises that this is an emerging technology, but that numerous technology issues remain to be solved for the medical devices industry. It is envisaged that RFID will not replace bar codes but work in parallel with them.

Authorities (worldwide) are at the same time reviewing and developing new requirements for UDI, serialisation and medical device traceability initiatives in order to improve patient safety. Due to the complexity of implementation most are working to a phased introduction of 3-5 years.

Eucomed represents diversified healthcare companies, with a wide range of products and services, which are committed to comply with these UDI requirements and use them at the appropriate level of their product packaging, following a risk-based approach*. Eucomed believes a risk-based approach is needed with regard to the implementation of medical device traceability with unit pack serialisation, evaluating the actual risk to patient safety and risk associated with counterfeiting and reimbursement fraud. Therefore, implementation of serialisation and medical device traceability should focus on the highest risk devices first and exempt those device categories where less risk exists because they are:

- a low potential risk to patient safety
- not perceived as liable for counterfeiting (e.g. product manufacturing process, cost)
- subject to a managed distribution chain (e.g. direct delivery from manufacturer to hospital)

In line with the above position, Eucomed would welcome a standardised approach for Unique Device Identification (UDI) systems for medical devices that would require the packaging of devices to bear a unique identifier using a technology-neutral standard. This unique identifier should adequately identify the device through distribution and use, and may include information on the Lot/Batch and/or Serial Number.

* Risk-based approach

Risk assessment is the determination of the quantitative value of risk related to a defined situation and must be the first step of any risk management process, establishing the basis for an informed decision on the risk management strategy (e.g. track & trace, unit serialisation). Amongst others, the following factors should be taken into account when establishing the risk profile of a specific group of medical devices:

1. Patient Safety
Risk of medical errors
Speed of product recalls
Classification (*which is an expression of the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the device*)
Risk of use/user error
Degree of invasiveness (*invasive versus surgically invasive versus implantable*)
Duration of use
2. Reimbursement Fraud:
List price (*official reimbursement price*)
Financing method
3. Counterfeiting:
Market access, control of distribution channels
Margin, sales volume, size/weight and transport costs
Counterfeiting process

Example of risk-based model application to define product identification and traceability for medical devices

Classification	Product Identification	Traceability
Class I	Yes ⁽¹⁾	No ⁽²⁾
Class IIa	Yes	No ⁽³⁾
Class IIb	Yes	Yes
Class III	Yes	Yes

Note:

This table serves as a guiding principle only. Each manufacturer, based on the risk assessment model (page 5), can identify those products that require traceability based on each product's individual risk profile.

(1) Manufacturers should aim at placing UDI on their product's packaging unless this is technically or physically not possible.

(2) & (3) Based on a risk assessment, Class I and Class IIa products should normally not be considered for traceability requirements.

UDI label requirements (machine-readable identification of the product packaging)

	Consumption Unit Pack ⁽⁴⁾		Shelf Pack	
	Mandatory	Optional	Mandatory	Optional
Class I	(not applicable)	GTIN ⁽⁵⁾	GTIN	Production Data
Class IIa	GTIN	Production Data	GTIN + Production Data	(mandatory)
Class IIb	GTIN	Production Data	GTIN + Production Data	(mandatory)
Class III	GTIN + Production Data	(mandatory)	GTIN + Production Data	(mandatory)

Note:

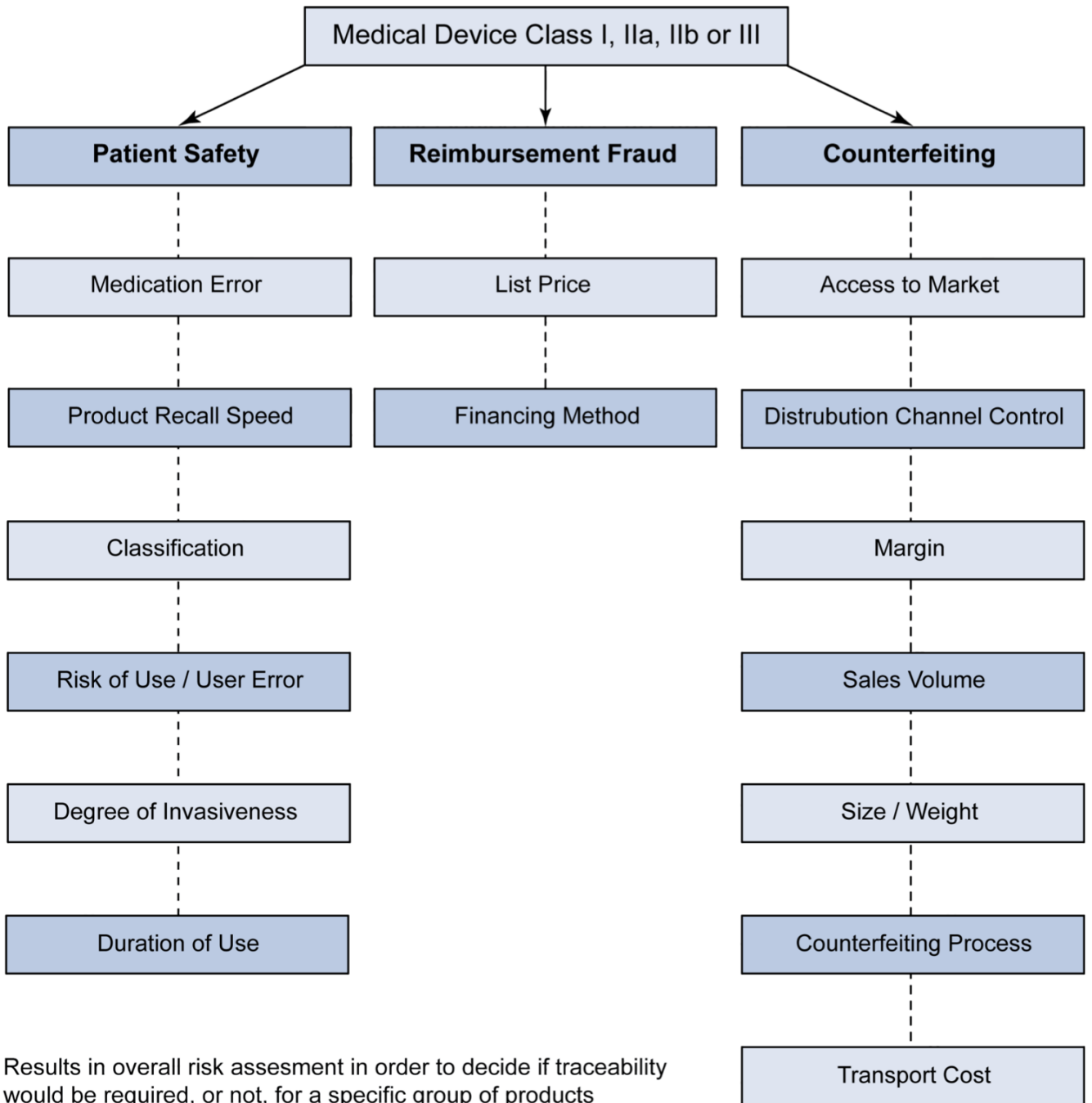
(4) Technical feasibility prerequisite (space, substrate etc.)

(5) Does not exclude the use of production data, which is at the manufacture's discretion

Production Data = Expiry Date + Lot Number or Serial Number

It is at the manufacturer's decision whether the product is 'Lot Number' or 'Serial Number' controlled

Example of risk-based model and criteria to apply to individual product groups



Example of risk-based model and criteria to apply to individual product groups

		Patient Safety					Reimbursement Fraud		Counterfeiting					Total			
		Medical Error	Product Recall Speed	Classification	Risk of Use / User Error	Degree of Invasiveness	Duration of Use	List Price (what is the official reimbursement price)	Financing Method (Hospital / Day Care - how it is financed)	Access to market	Distribution Channel Control	Margin	Sales Volume	Size / Weight	Counterfeiting process	Transport cost	Risk
Class I	A																
	B																
	C																
Class IIa	A																
	B																
	C																
Class IIb	A																
	B																
	C																
Class III	A																
	B																
	C																

Note: Cells A, B & C (the list can be extended) are used to identify each of the manufacturer's products, for each Class of medical device.

Glossary of terms:

Unique Device Identification (UDI):

Systems, for medical devices, that would require the label or pack to bear a unique identifier (i.e. GTIN) using a technology-neutral standard. This unique identifier should adequately identify the device through distribution and use, and may include, in addition, information on the Lot/Batch and/or Serial Number.

Global Trade Item Number (GTIN):

A standardised, unique identification of trade items worldwide. GTINs may be 14, 13, 12 or 8 digits in length. Their data structures require up to 14 digit fields, and all GTIN databases and processing software should allow for 14 digits (see table below). All healthcare databases (excluding retail point-of-sale) must always use a 14 digit construction to allow storage of all GTIN data structures. For GTIN-13, 12 or 8, leading zeros must accommodate the digit positions that are not appearing when encoded. For example, healthcare databases for registration, traceability, distribution or reimbursement of healthcare products must accommodate all GTIN data structures including GTIN-14. A trade item is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as all their different configurations in different types of packaging.

	Data Structure													
	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆	T ₇	T ₈	T ₉	T ₁₀	T ₁₁	T ₁₂	T ₁₃	T ₁₄
GTIN-14	N ₁ *	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄
GTIN-13	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃
GTIN-12	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂
GTIN-8	0	0	0	0	0	0	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈

* Indicator Digit

Risk assessment:

Risk assessment is the determination of the quantitative value of risk related to a concrete situation and must be the first step of any risk management process, establishing the basis for an informed decision on the risk management strategy (e.g. unit serialisation, traceability).

Track and Trace:

Generally, track and trace is the ability to track forward; the movement through specified stage(s) of the extended supply chain and trace backward; the history, application or location of that which is under consideration.

Managed Distribution Chain:

System of distribution where the manufacturer delivers the medical device directly to the healthcare setting where the product will be dispensed to the patient, without any involvement of third parties, such as wholesale distributors or traders of medical devices.

Serialisation:

The equipping of production lines with real-time in-line coding and printing equipment to mark each individual pack with a unique identifier containing a serial number, which should preferably remain technology neutral. For the purpose of this Eucomed guidance document, traceability labelling - when required - should ideally be applied to the saleable unit level of packaging for every product group (one saleable unit may however contain many individually packaged units of use).

Eucomed is the Voice of the medical technology industry in Europe. Eucomed represents directly and indirectly 4,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Eucomed members include national trade and pan-European product associations and internationally active manufacturers of all types of medical technology. The mission of Eucomed is to improve patient and clinician access to modern, innovative and reliable medical technology.

For further information please contact:

*Place des Maieurs, 2
1150 Woluwe St. Pierre
Belgium*

*Tel. +32 2 772 22 12
www.eucomed.org
email. info@eucomed.org*