

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:

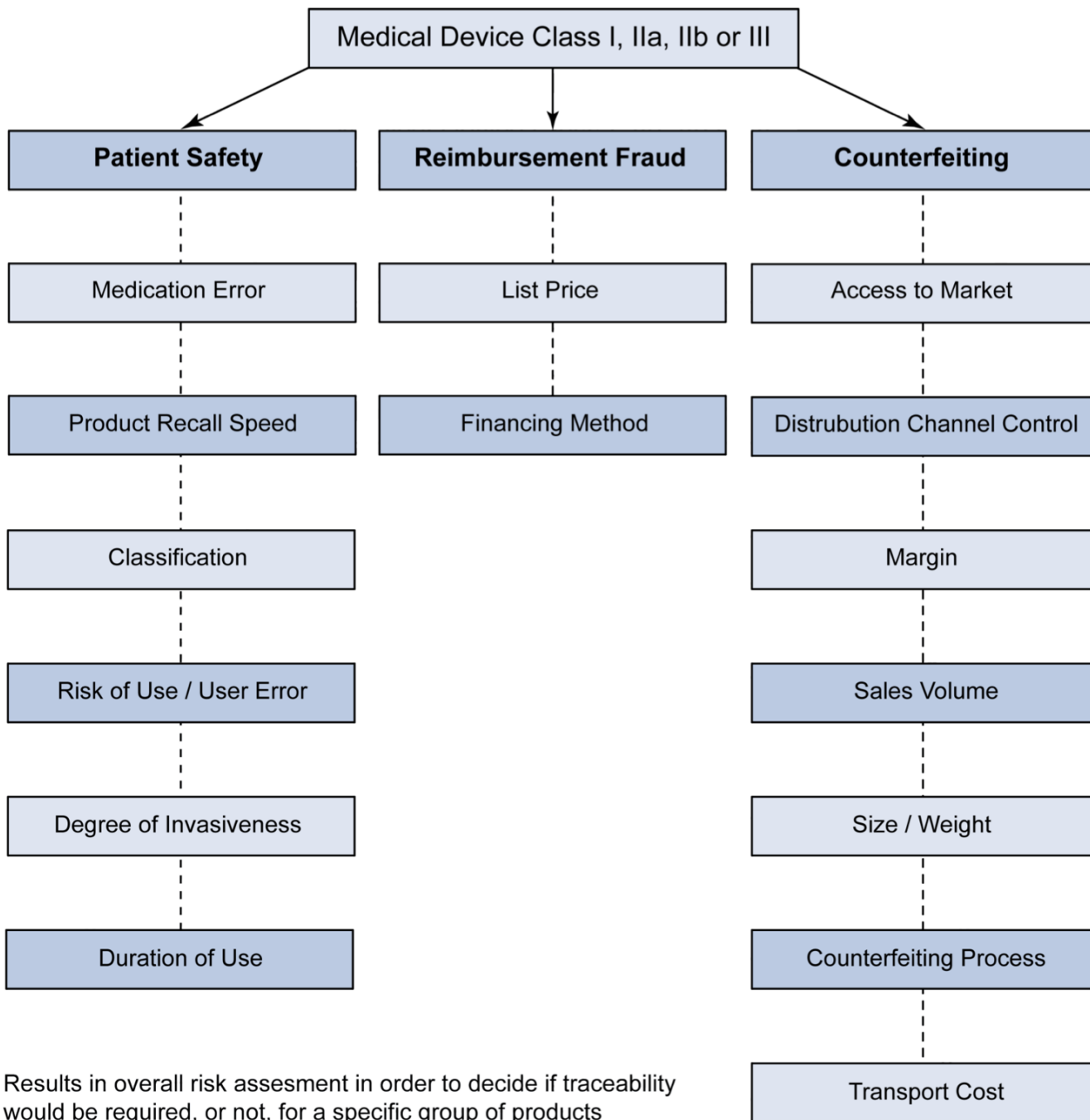
(4) Technical feasibility prerequisite (space, substrate etc.)

(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.

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