Background

- Eucomed ETF Group
- Remit of Group
  - AIDC
  - E-business including distribution
- Involvement with GS1 Healthcare



New Developments in AIDC since January

- Revised Guidance on Bar Coding
- Survey of members 2006 and 2007 (in progress)
- Background Paper
- UDI - Japan and USA

Eucomed Guidance on Bar Coding for Medical Devices

Eucomed Guidance on Bar Coding for Medical Devices

For many years, medical device companies around the globe have endeavoured to optimise their internal logistics processes. The use of bar codes has contributed to these efforts, because they have a proven track record for facilitating speedy and accurate receipt, verification, stock control and shipping transactions. Previously a company's bar code strategy was mainly focused internally, between their own manufacturing facilities, labelling sites and distribution centres. In the best case, the strategy included specific vendors and/or larger strategic customers.

In the last 5 years bar coding and product identification has been drawn to the attention of a wider audience. This is due to increasing awareness of the importance of patient safety, interest from social security systems, an increased focus on device tracking and the reduction of counterfeiting. From component manufacturers, all the way through the supply chain to the end of patient care, the desire has grown to have a common set of rules and standards, allowing each participant to read and to interpret data provided in a bar code format and to be able to identify products/packs at any point in time, through a database.

With end users being confronted with different bar code types and formats containing different data elements (or in some cases no bar code at all), both industry and the wider healthcare community have started to demand that bar code standards be aligned globally. Unless this alignment takes place, manufacturers and others in the supply chain will see the complexity of packaging and labelling increase dramatically as a result of customers creating their own requirements. Furthermore, regulators and authorities will impose regional or country specific requirements, with the risk of compromising both patient safety and supply chain efficiency.

The creation of GS1 Healthcare (formerly GS1 HUG™ [global Healthcare User Group]) in 2005, with participation from manufacturers and suppliers worldwide, has acknowledged the importance of the existing GS1 (formerly UCC/EAN) standards. Furthermore GS1 Healthcare ensures the involvement of all key parties in the supply chain with the ultimate benefit of improved patient safety. Today GS1 Healthcare offers a forum in which, authorities, healthcare providers, healthcare professionals, health insurance companies, pharmacies, manufacturers and distributors can discuss their requirements. This open interaction has resulted in recommendations to further develop and fine-tune existing GS1 standards (e.g. Healthcare GTIN Allocation Rules). It has also identified the need, if necessary, to create new standards due to the development of new technologies or changes in business and healthcare requirements or practices.

Eucomed supports the work of GS1 Healthcare, for the reasons described above.

Eucomed recommends that its members consider the adoption, or increased use of GS1 standards when:

- Developing a bar code strategy, taking into account the choice of linear and/or two dimensional (2-D data matrix) bar code types, the latter being beneficial when small packs and labels are involved, although currently not widely requested or regulated for medical devices
- Reviewing a company's existing bar code strategy, taking into account regulations and customer's needs *(additional variable information e.g. LOT/Batch No., Use by Date, Serial Number, that are supported with Application Identifiers),* and updating scanners

and verifiers to ensure that they can handle both linear and 2-D bar codes
- Making revision to or re-designing products or product labels and packaging (note: implementing a bar code often requires a re-design of label/pack format and content)
- Developing and introducing new products or introducing product range extensions
- Changing packaging or labelling configurations
- Updating label/pack printing software, ensuring that it meets all current GS1 standards including GS1-128 Linear and Data Matrix symbologies
- Adding additional languages to labelling or introducing language specific labelling (note: each language specific product would require a different GTIN *[global trade item number]* for each language version and each packaging level)
- Reducing the risk of products being counterfeited
- Improving track and trace efficiency
- Tendering, that requires either printed and/or electronic bar code data
- Considering requests for direct part marking (2-D bar codes)

Eucomed does not expect companies to introduce or change bar code strategy overnight, as implementation can be a lengthy process – it might take the lifetime of a device (shelf life) to have warehouse and consignment inventory refreshed to:

1. Fully benefit from the availability of bar coded products/packs on the shelves and
2. Allow companies to cease labour intensive, supplemental over-labelling activities

Eucomed recommends introducing the use of GS1 standards at any opportunity deemed appropriate or from a cost-efficiency and quality point of view.

Eucomed believes that companies implementing these standards will be best positioned to meet customer expectations now and in the future and to satisfy the increasing requirement for electronic information exchange. This will improve patient safety and will create the opportunity for business growth.

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Eucomed *represents 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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Medical Device Industry meeting with EU Commission on UDI

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COCIR - EDMA - Eucomed

CEC:

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Medical Technology

Purpose of meeting:

The CEC had requested the meeting to hear industry views prior to meeting of authorities called by FDA end of January

Industry delegation emphasised the following:

- Standards must be global
- Member States should refrain from local regulation which are not aligned with the global approach
- The focus must be on Patient Safety
- Healthcare providers must be fully engaged
- Device Identifiers to be assigned by the manufacturer
- A risk based approach is essential

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Industry delegation emphasised the following:

- Flexibility is essential – some products cannot (currently) be marked
- The meaning of 'Unique' needs clarification – this is NOT serialisation
- Dataset should be single / world-wide and minimum
- Solutions should be 'technology agnostic'
- Access to data by third parties must be limited
- Ownership of product data must be with the manufacturer

Discussion highlighted the following:

- CEC concerns that ISO are looking at international nomenclature as the result of a WHO initiative.
- Healthcare Providers are outside the competence of both CEC and FDA
- An appropriate transition period is essential for a successful implementation with no retroactive requirement

Other Developments

- Revised guidance on Good Distribution Practice

Conclusion

ETF/Eucomed moving to new phase

Phase 1

- Develop/debate/alignment with GS1 Healthcare

Phase 2

- Implementation and vigilance
- Engagement with EU Commission
- Counterfeiting
- Alignment with EDMA & COCIR
- Promotion of the message
- Vigilance
  - monitoring EU & global developments
  - representing member's interests, particularly where there are national variations (e.g. unit level marking)

Do you have any questions?

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