Labeling Task Group Update

Healthpack'08
San Antonio, TX

Topic overview

- E Labeling progress or lack thereof in the EU
- Development of a guidance document for PS labeling of medical device packaging
- RFID label update
- Labeling, sustainability and Packaging Waste Directives

The looong proposed E labeling directive…….

- “In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means”.

- Amendment to Article 11…..the following paragraph is added:
  “14. The Commission may, in accordance with the procedure referred to in Article 7(2), adopt measures allowing instructions for use to be provided by other means.”

E Labeling status in the EU…..not much new from last year

- Updated MDD no longer expressly prohibits E Labeling.
- Europe – Adoption of proposal expected on the first reading.
- Proposed MDD acceptance likely to occur ????
- Asia – Move toward E Labeling, CD ROM widely accepted. Japan modeling requirments after EU; Hong Kong has accepted E Labeling
- Eucomed and Global Harmonization task force have come up with guidelines for safe and effective labeling

Key points – E Labeling

- Directive acceptance expected
- Countries can still individually dictate how they will accept IFU's
- Consult with your notified body to see if your product is eligible for E labeling in a specific country.
- Pay close attention to rev control, access, proof of delivery, language requirements, security, etc.
- CD's with product has generally been acceptable with notified bodies.
- Research specifics for your device in each regulated region you are going to distribute in and be aware of 'nuances'.

Medical device package label guidance document

- Overview available on the IOPP website at http://www.iopp.org/files/LabelQualplan.pdf?pageid=pageid

- Liasion with ASTM Label Task Group D10.14 and the D40 adhesive group. No chair for adhesive group at this time.

- Performance criteria matrix under review; focus is now corrugated but surfaces should be expanded

RFID labeling

- Very little ‘single use’ tags, mainly batches
- Best ROI on internal driven systems vs Walmart or DOD driven and mandated systems
- Most use VHF, Class 1, Gen II tags – 24 characters, 4 meter read range
- Costs has dropped from .50 to .15 each
- Combo bar code/RFID used in some pharm large lot bags.
- New VHF out this year with 60 plus character capability
- Some early studies in medical device in process

RFID continued……

- **Medical device usage issues:**
- Sterilization techniques can cause damage
- 95-98% is the best success percentage at this point
- Tag or antenna can't be printed over; real estate scarce on 27 language product labels

Sustainable labels and packaging

EU's Packaging and Packaging Waste Directive's 3 essential requirements

-Source reduction

-Minimal presence of hazardous components

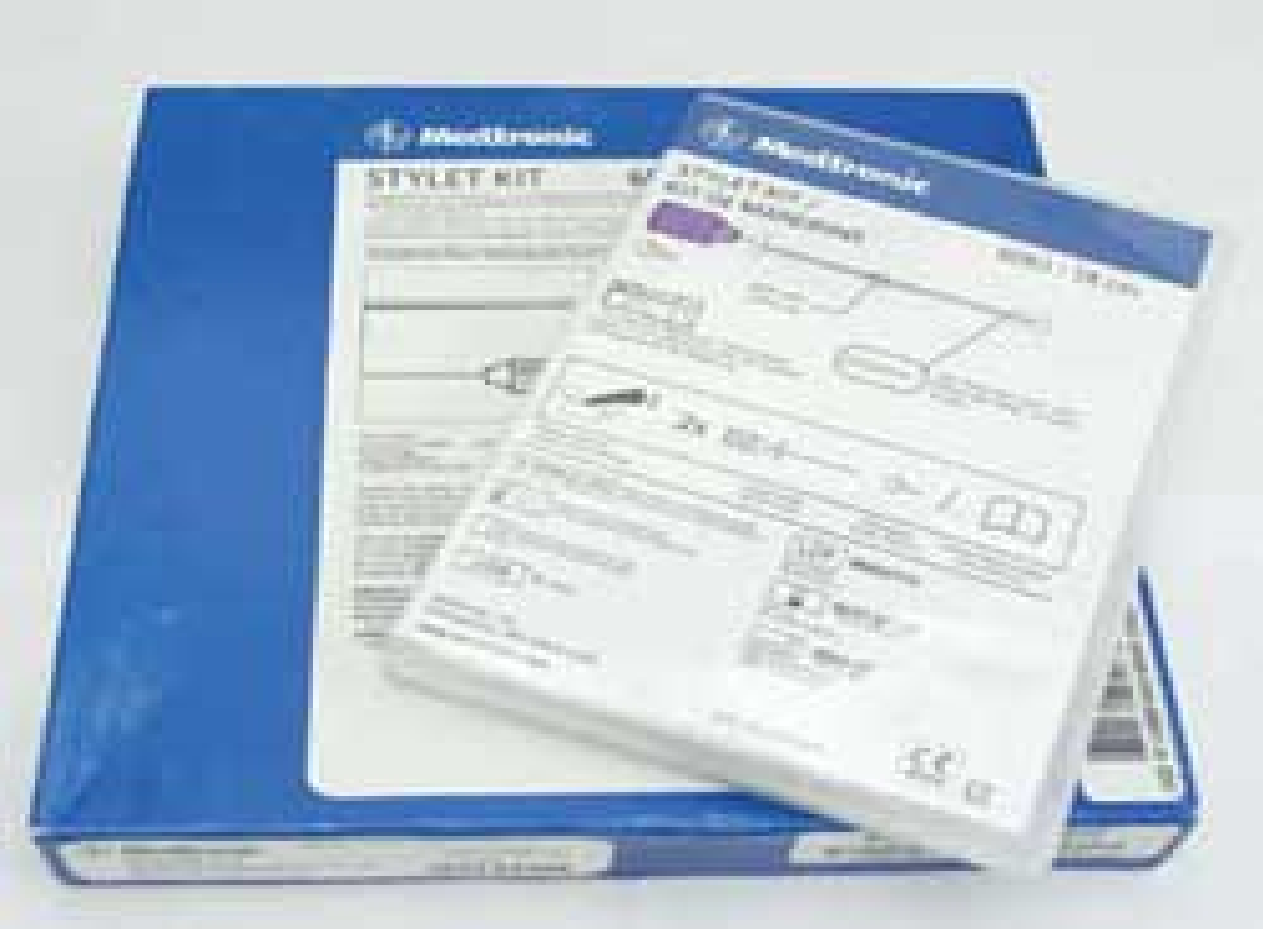
-Recovery, reuse, and recycling

Label sustainability iniatives

- Paper weight - Basis has gone from mostly 60# down to 47-50# sheets.
- Adhesives – solvents have been mainly replaced by water based acrylic emulsions.
- Liner – Thinner, super calendered liners are becoming more popular

Case Study – MDT Stylet Package

Governors Award – MnGreat 2007 – MPCA



Label and package goals & components

- Source reduction – smaller package, fewer components, weighs less, e labeling eliminates weight and paper waste
- Minimize toxicity – PVC trays eliminated in favor of pouches
- Recycling/reuse – Annual reduction of 500,000# of packaging waste, potential 190,000# if packages are recycled, and $2.3million cost savings over 2 years.

Labeling Task Group Members

- Dave Olson, Advanced Web – Chair
- Mark Andersen, BSCI
- Ryan Cannon, American Medical Systems
- Jan Gates, Abbot Vascular Cardiac Therapy
- Gerry Gunderson, Quality Tech Services
- Susan Ritter, Tyco Healthcare/Valleylab
- Judy Salzer, Medtronic CRDM