Implementation of serialisation & traceability at manufacturers – best practices

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About Sanquin

• Founded January 1998

• Sanquin is a merger between Central Laboratory of the Red Cross Blood Transfusion Service (CLB, founded WOI) and the Dutch Red Cross blood banks

• Sanquin is responsible for supplying blood in The Netherlands on a not-for-profit basis - donors give blood on a voluntary basis

• 5 divisions: Blood Bank, Plasma Products, Reagents, Diagnostic Services & Research
Production of human pharmaceuticals

- Sanquin registrations
  - National Marketing Authorisation procedure: 5 products
  - EU- Mutual Recognition Procedure: 5 products
  - European Medicines Agency: 1 product

- Production for Contract Manufacturing

- Delivery of products to:
  - EU
  - Switzerland
  - Turkey
  - Australia
  - US
  - Canada
  - Brazil
  - Indonesia
Plasma Products & Traceability

• Traceability of plasma products
  • 1993: Dutch Law - batch administration Dutch hospitals for some products
  • 1996: HIBC barcode & peel off labels & leaflet: Lot
  • 1997: Change of law - Plasma products became human pharmaceuticals
    • Registration national, MRP, EMA

• Human pharmaceuticals:
  • European Federation of Pharmaceutical Industries and Associations
    • 2006: all secondary packing materials: GS1 Datamatrix
  • Dutch Symposium 2010: bedside scanning
  • EU-directive Falsified Medicine published July 2011
  • Meeting with Dutch Hospital Pharmacists Association (NVZA): bedside scanning
What to do to implement GS1 Datamatrix

• Become a member of GS1
  • 2002: company code: 871718583
  • 2009: EAN-13 to Dutch cartons

• Identify Application Identifiers (AI): (01)GTIN (17) EXP (10) Lot
  • new AI needed Active Potency: (7004)

• Create a S.O.P. with products and GTIN
• Investigate which packaging materials had to change
• Can packaging machines print datamatrix?
• Distribution department
• Validations
• Training
Sanquin packaging materials

• All labels were adjusted
• All cartons were adjusted

• Artwork was sent to regulatory authorities
  • EMA: great help to get all text on the labels (8 ml vial – 3 languages!)
  • MRP: questions about GTIN
  • National Authority: no questions
Packaging department
Distribution department

- SAP Sales module adjusted
  - Products with HIBC or Datamatrix (GS1)
  - New scanners (camera-based): linear and 2-dimensional
  - Computer validation (GAMP)
Status

• National: week 45 2013 1st product was delivered
• MRP: 3 products: GTIN included on 2
• EMA: 1 product: GTIN included & delivered to NL, FI, B
Special issues
Bedside scanning: vial (1)

- One pack with 2 different vials: water for injections and freeze dried product
  - 3 different GTINs: carton, 2 vials

- Size of datamatrix on labels – 2ml, 8ml, 15ml, 50ml, 100 ml, 250 ml, 500 ml vials

- New label 2 ml vial
Bedside scanning vial (2)

- Too much regulatory text on vials
- Space needed for the GTIN number & 2D-code
- Some countries do not allow a turn-around label
- Some countries require 2 peel off labels
Local Database needed?

• Database Belgium?
  • Sanquin products: 2 products with datamatrix
  • CAF-DCF: 2 products with datamatrix

• Database Finland?

• How can a distributor add to a local data base.
  (Not every one speaks local language)
A special human pharmaceutical

- Pooled plasma product
- Product is distributed by Blood Banks: ISBT-128
  - NL – 5 barcodes
  - Unit number
  - Blood group code
  - Product code
  - EXP date
  - Pharmaceutical code
- traceability on “unit number” = serial number
- Is there a need for datamatrix according to EU directive FM
  - IT problem Blood Banks & hospitals?
More countries on one pack

- EMA- registration: Cinryze (Sanquin = manufacturer & distributor)
  - Two countries one pack: UK & Germany
  - Two countries one pack: Finland & The Netherlands
    - Vnr code and GTIN code: do we need to add Vnr as (AI)
      - Only one datamatrix on carton
      - Will Dutch customers be able to handle the AI: Vnr-code
Medical devices

• Medical devices in an administration kit delivered together with a pharmaceutical product
  • composed according to article 12 of the directive medical devices 93/42/EEC.
  • No CE logo

• Medical devices in a pharmaceutical pack

• Serialisation needed in the future???

• SAP: Display batch - Where used list
Complaints of customers

• Dutch hospital: cannot read datamatrix

Sales manager upset
Status Serialisation

• All machines can print a serial number

• Do we need to print serial numbers (20 characters) on the product carton?

• SAP and production machines are not linked – project starts end 2014
  • How do we cope with GTIN on vials
  • 3 GTIN per product!

• Datamatrix is printed on the site of cartons – aggregation problem?
  • Not a lot of space on top of the small cartons (34 x 34 mm)
Special thanks..

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