

# Primary Pack Coding of Generic Medicines

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Hello, I'm Chris Fordham

- Located in North Devon in the UK, at a solid oral dose manufacturing facility
- 16 years working in pharma packaging, with the last 5 managing Accord's FMD function, more recently starting to work on primary pack coding and EPIL
- Represent Accord Healthcare on Medicine's for Europe's Anti Counterfeit Steering Committee
- Looking after Accord's interests for Packaging Technology and new initiatives across all EU markets (and UK!)



## What are we (manufacturers) being asked to do?

- Apply data rich coding to primary packs of medicine (both human and machine readable)
- Non-serialised coding – data remains static across a batch, and is not reported to any national or supra-national system (i.e. not FMD!)
- Most current requests relate to products for hospital supply, although not always
- Inclusion of this coding is now commonly a feature of tender award criteria

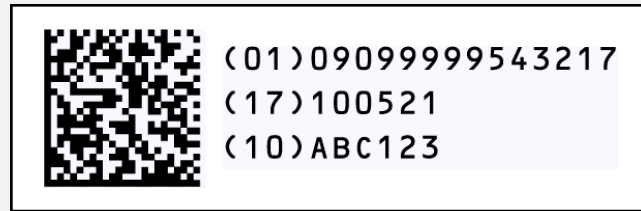


### Where can we look for guidance?

- GS1 clearly defines standards for machine readable coding in many formats:



DataBar



DataMatrix



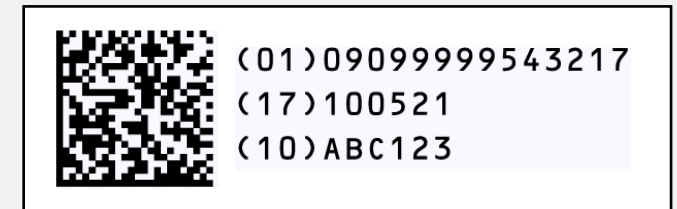
DataMatrix

- Which elements do we need to incorporate in the machine coding and human readable?
  - GTIN ✓
  - Lot Number ✓✓
  - Expiry ✓✓✓
- Application of coding at 'just' primary level, or repeated on each product cavity (for instance)?

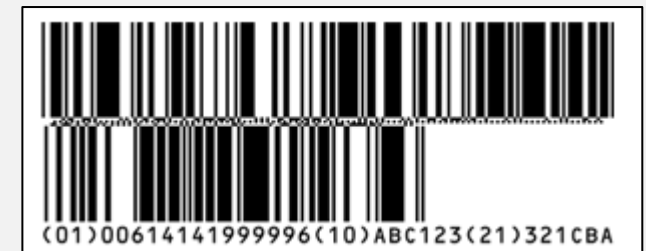


### ISO Standards (examples)

- ISO/IEC 16022 - Data Matrix symbology characteristics, data character encodation, symbol formats, dimensions and print quality requirements, error correction rules, decoding algorithm, and user-selectable application parameters.
- ISO/IEC 15415 - Bar code symbol print quality test specification — Two-dimensional symbols

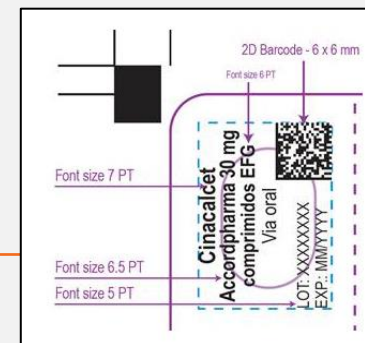


- ISO/IEC 24724 - GS1 DataBar bar code symbology specification
- ISO/IEC 15416 - Bar code print quality test specification — Linear symbols



## What makes this difficult?

- S P A C E ! ...and technology
  - Labels and blisters vary in size and are typically optimised for best pack cost and transportation
  - Materials used for primary packages are often highly reflective (glossy labels and aluminium lidding foils), which makes achieving quality grading challenging
  - High speed processing coupled with need for highly accurate code placement, or even secondary processes to add coding
- Content and Consistency
  - Commonality between data elements required across markets:
    - Human readable data prompts
    - Coding elements to be incorporated in machine readable code, and human readable
    - Different standards being applied to regulatory submissions by NCAs and EMA



## What does the whitepaper set out to achieve?

- Consistency in near term projects as national and European approaches are defined
- Educate health authorities, tender bodies and end users on the challenges posed to manufacturers
- Apply the benefits of knowledge gained during the roll out of FMD
- Start a conversation which leads to a standardised approach to primary coding, enabling future links to EPIL and new multi market pack opportunities
- Readability Guideline: Ensure that national competent authorities and the EMA consider that primary packs fit the 'small containers' description, and therefore more pragmatic positions on font sizes and layouts can be taken





We want more events like this!

- Sharing experience and knowledge, supporting industry and asking questions

Similarities to FMD?

Share and discuss the Whitepaper with anyone and everyone – the more switched on people the better!

Thank you!