FiMVO
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Medicines Verification in a Pharma Company

1 February 2018

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Falsified Medicines Directive & Delegated Regulation

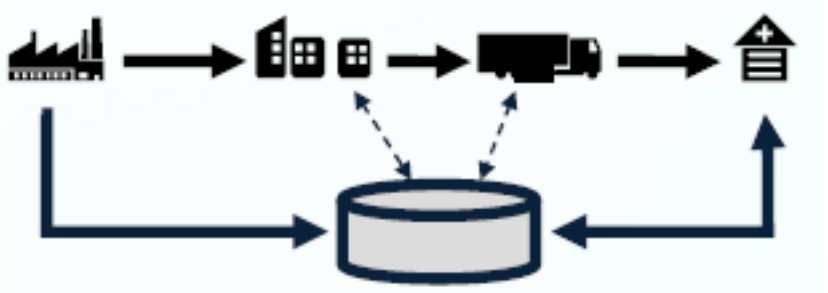
9 February 2019

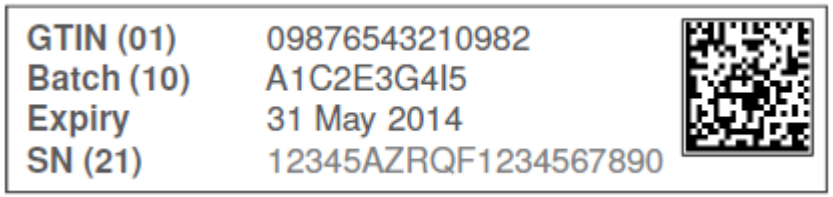
Mandatory verification of all packs in scope

- Major change for the pharma companies
  - Globally
  - Regionally
  - Locally

EU Safety features and verification

- Unique Identifier (UI)
- Tamper evident devices
- Medicines Verification System





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Impact to pharma companies

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Global impact & complexity

- Serialization is NOT only an EU requirement
- Manufacturing sites globally need to have the capability to meet the requirements.
- EU requirements apply for 28 countries
  - Potentially 28 slightly different approaches

Regional impact & complexity

- Within EU medicinal products are handled differently
  - Centrally approved products
  - Nationally approved products
- Data management
  - Master Data
  - 1 OBP, multiple MAHs

Local impact & complexity

- Implementation of Safety Features
  - Differences in coding requirements
  - Timely update of artworks
  - Timely information to all stakeholders
  - Close collaboration with distributor
  - Contract with NMVO

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Summary

- Medicines verification impacts all layers
- Time is running out! Act now!