

# Preparing the Supply Chain

Update 05.2017 – Version 1.0

Based on the information available at that date of NCA.



# Starting Point

- Check if your company is **affected**: check the scope of the Falsified Medicines Directive (FMD) = Download general presentation of 24/04/2017 and do the check of product types (Excel)
- Ensure your company is **well informed** and all involved departments are up to speed. The FMD is a major change for the pharmaceutical industry and we have no way back. All departments are involved:
  - Sales: customer requirements can change
  - Customer Service: Helping and ensuring system works
  - Regulatory Affairs: Update Marketing Authorisations
  - Artworks: Adapt artworks for 2D and ATD
  - Quality Affairs: Adjust Standard Operating Procedures
  - Medical Affairs:...
  - IT Infrastructure: make sure large new set up is integrated and works within set required response times.
  - Supply Chain: adjust production requirements
- Are **your suppliers** informed/ready: internal production or Contract Manufacturing Organisation.

# Getting started – SYSTEMS

- On boarding to the EMVO: local or global strategy  
As MaH all data is uploaded through central European Hub  
So being part of it is crucial
- On boarding to the BeMVO – GDMVO:  
If you want to operate on certain markets
- On boarding to GS1 : local or global strategy + Set Up
- Internal IT infrastructure:
  - Serial Numbers generator: internal or at CMO(: Level 0)
  - Serial Number exchanger: communication platform (: Level 4)
  - Integration Limps/ERP of set up: necessity?
  - Master Data Enhancement ERP: Requirements & set up.

# Getting Started – Supply Chain

Make sure your production facilities (: internal and/or external) are informed and ready to perform necessary requirements:

- **2D Barcode –aligned to ISO standard**

- with SN for products in scope
- without SN for products out of scope

The Substrate (Type of board used) and printing methodology are crucial to obtain set quality standards set out by the regulation!

e.g. Tambrite and Laser printing do not match!

- **ATD Device:**

- Mandatory for products in scope
- Voluntary for products out of scope

Tamper evidence can be reached through multiple techniques: Mechanical, Gluing, Labels, Cellophane, ... ensure correct equipment

# Supply Costs

Costs related to FMD can be split for the Supply Chain into:

- **Set Up Costs**

Adjusting Production Lines estimated up to 200K € per packaging line & related IT systems is a high cost. (Source: Systech)

If number of products involved is limited boxes could be printed up front with the 2D Barcode and labelled for the required ATD, but off line is always less cost effective so make your analysis correctly!

*Aggregation in EU zone is not mandatory but implementing at later stage could mean an additional cost on the packaging line of 200K €!*

*So make your analysis correctly and ensure timely ordering of necessary tools & equipment (hard & software)*

- **Variable Costs**

Variable cost calculations show the cost would be given in line and global set up cheaper than the existing Sequential Barcode system.

# Open Issues List

- **Scope** definition and security **BE**: still not published
- **Alignment** of scope definition with **GDL**
- **Collaboration Set Up** with GDL NMVO
- **GTIN – CNK** conversion table for RIZIV: database conversion table and set up timelines secured.
- EU Hub Audit & implementation of **Multi country pack** set up

*⇒ Overall a lot of strategic decisions to be taken internally & aligning with external partners – NCA: Taking time to implement so start NOW!*

# Conclusion

- **No way back 02/2019** is the deadline! And multiple things to do with important deadlines and multiple departments & companies involved!
- **BeMVO is ready to assist** for early birds participating to the testing periods: cf. Timelines general presentation of 24/04/2017
- **Early Bird discount set up:** if you ensure early subscription to the BeMVO you will get interesting discounts!
- Some **CMO's will not be interested** to apply the FMD so you will have to shift from supplier!

