EU FMD ARTWORK COMPLIANCE VISUAL EGUIDE

CRUCIAL QUESTIONS

The global pharma market faces unprecedented complexities and pressures regarding the packaging and labelling of medicinal products. Ahead of the 2017 Packaging and Labelling Summit, this guide examines the changes required for pharmaceutical packaging to meet the requirements of EU Falsified Medicines Directive (FMD) and the crucial questions to ask in order to achieve compliance.

THIS GUIDE COVERS THE FOLLOWING AREAS:

- EU FMD packaging related requirements
- Broader organisation and supply chain implications
- Unique identifiers (UID)
- Anti-tampering solutions
- Artwork design
- Implementation guidance
- Where to get more help
- About the Packaging and Labelling 2017 Summit

PRODUCT PACK PRE-FMD IMPLEMENTATION:

SECTION 1 - WHAT THE EU FMD REQUIRES

EU FMD PACKAGING RELATED REQUIREMENTS TO BE APPLIED BY FEBRUARY 2019:

Application of a unique identifier to the outer packaging of the medicinal product, or to the immediate packaging if the medicinal product has no outer packaging

Inclusion of an anti-tampering device to the outer packaging of the medicinal product, or to the immediate packaging if the medicinal product has no outer packaging

Tip: Lot & Expiry human readable text are required by other existing regulations

SINGLE UNIQUE IDENTIFIER

GTIN: 12345678901234
LOT: AA11BB
EXP: 116619
SN: 12345X789XX234

- GS1 DataMatrix or complying to ISO/IEC 16022:2006
- Print quality of at least 1.5 ISO/IEC 15415:2011
- Smooth, uniform, non-reflecting surface
- Small packs exempt from text requirements
- Where required, addition of a national reimbursement number

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ANTI-TAMPERING DEVICE

GLUE | STICKER

SECTION 2
SUPPLY CHAIN IMPLICATIONS FROM PACKAGING REQUIREMENTS

Some of the supply chain implications of the packaging related FMD requirements to consider include the following:

EQUIPMENT & SYSTEMS

- Packaging & information technology systems to apply marking and anti-tampering requirements
- Meeting Aggregation requirements

CHANGE CONTROL

- Space requirements and the potential need for physical pack changes
- Cascading new requirements through in-company and supply chain partner processes and systems
- Product release verification changes
- Other product identification coding requirements during transition and beyond

QUALITY CONTROL

- Packaging component specification control to ensure print surface is consistently adequate
- Quality Control requirements for packaging components, packaging marking and anti-tampering
- Packaging testing to ensure pack marking and anti-tampering longevity in the supply chain
- Where detailed pack marking and anti-tampering requirements will be specified & controlled

MULTI-MARKET / SITE DISTRIBUTION

- Product coding restrictions on multi-market pack groupings
- Brand image and product security consistency across products, sites and packaging lines

SECTION 3
UNIQUE IDENTIFIER AND ON-LINE PRINTING CONSIDERATIONS

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- 2D symbology to use – GS1 DataMatrix
- Data Matrix detailed specifications, e.g. cell size
- Market specific required data elements
- Covert anticounterfeiting features
- Quiet zones around Data Matrix
- Pack marking technology e.g. Inkjet, laser
- Small pack text requirements
- Pack marking equipment restrictions e.g. pack faces, orientation, size of print, speed
- Data element fixed test in particular market(s)
- Font type & font size considerations e.g. minimum font size, machine verification
- Length & randomisation of serial number

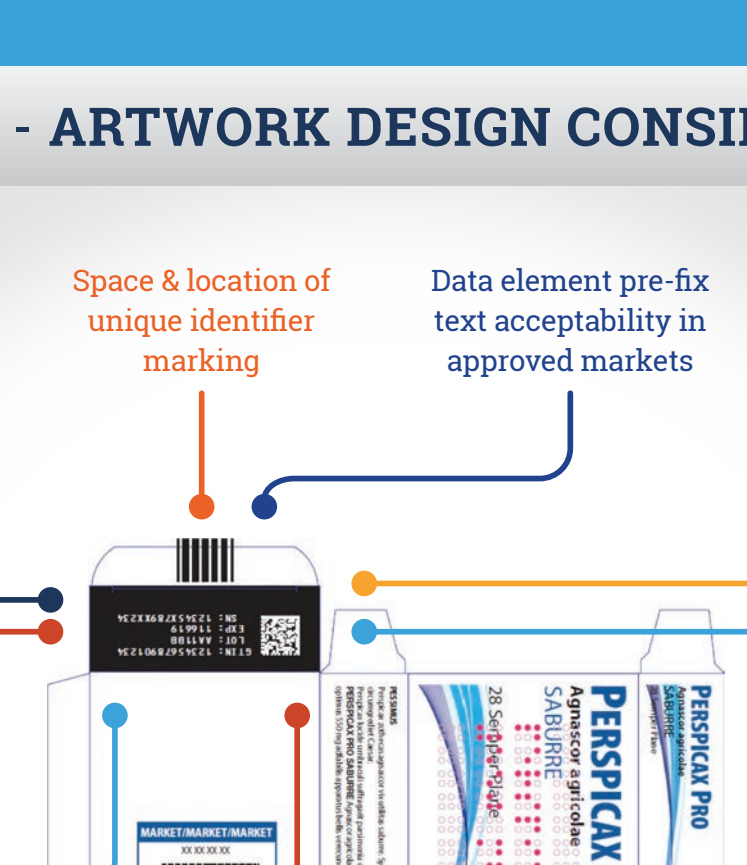
SECTION 4 - ANTI-TAMPERING CONSIDERATIONS

SIZE, SPECIFICATION & LOCATION OF SEALS | **WHAT GLUE TYPE(S) WILL BE USED?**

- Types of anti-tampering technology to use e.g. transparent seal, enhanced seal, glue, mechanical
- Brand image & product security consistency across products, sites & packaging lines
- Pack surface specification where seal or glue will be applied
- Packaging line equipment / process restrictions e.g. size, location, orientation
- Other benefits / features of sealing technology e.g. covert anti-counterfeiting

SECTION 5 - ARTWORK DESIGN CONSIDERATIONS

- Type of marking and requirements of artwork e.g. laser ablation layers
- Space & location of unique identifier marking
- Data element pre-fix text acceptability in approved markets
- Pack marking equipment restrictions e.g. pack faces, orientation, size of print, speed
- Avoid multiple visible barcodes on unique identifier face of pack
- Smooth, uniform, non-reflective surface where Data Matrix applied



- Single or multi-face marking
- Data element pre-fix text acceptability in approved markets
- Other product identification coding requirements in transition & beyond
- Anti-tamper technology restrictions e.g. size, location, orientation
- Identification of anti-tamper feature location & surface specification
- Tamper evidence seal location & impact on underlying artwork

SECTION 6 - IMPLEMENTATION CONSIDERATIONS

Do you understand the legislation & possible issues ahead?
- Legislation understanding & uncertainties
- Define organisation response
- Identify regulatory issues

Have you identified which products will be impacted?
- Which packs impacted
- Multi-market & multi-sourced packs identified

What supply chain locations and packing lines will need to be upgraded?
- SC locations & packing lines identified
- Required capabilities for each understood

What are the packaging equipment and process constraints?
- Equipment & operational constraints on pack marking and anti-tamper identified

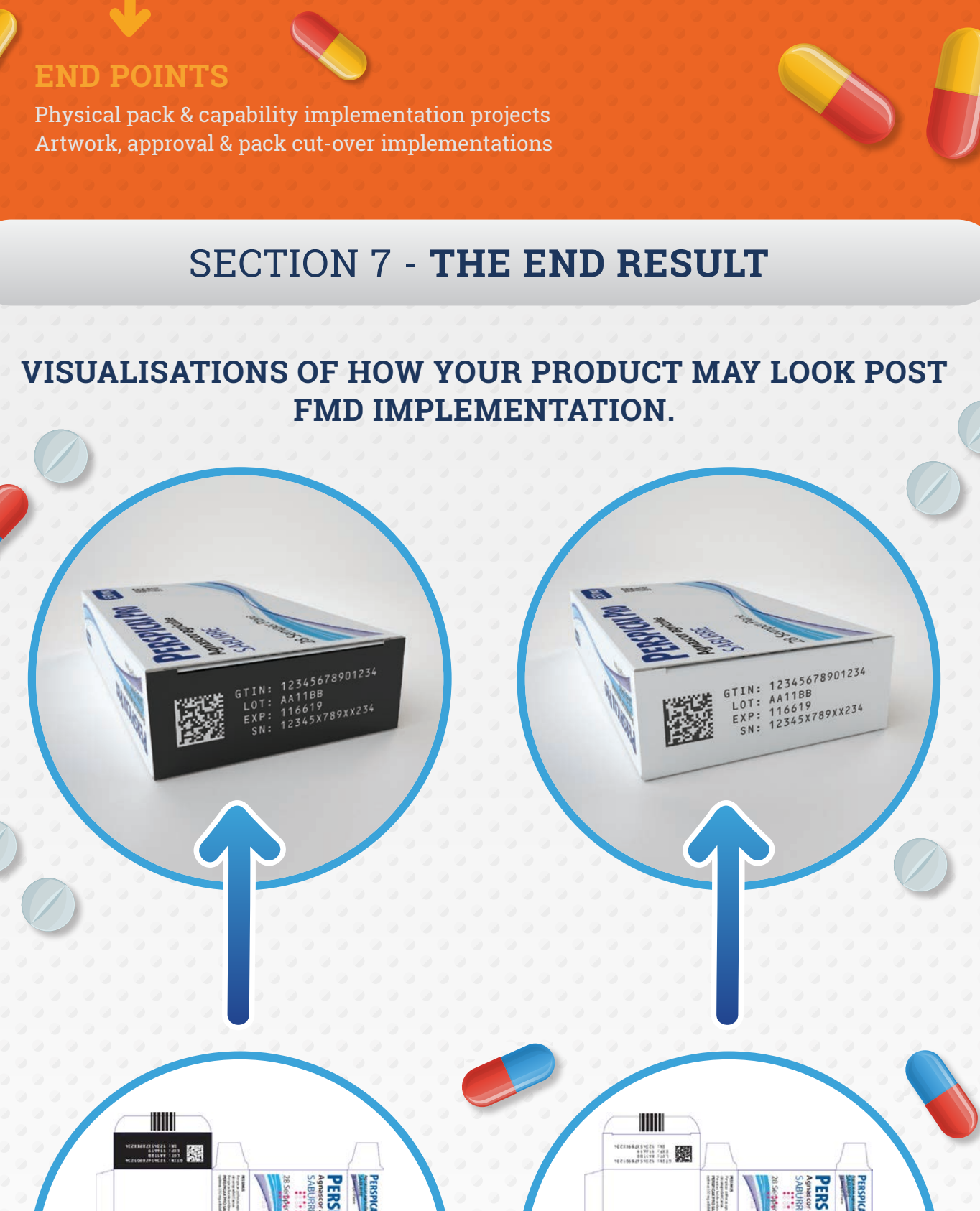
Do you understand the detailed pack marking?
- Pack changes defined
- Issues identified and resolved

Have you planned out your implementation program, step by step?
- Work breakdown defined
- Implementation projects planned

END POINTS
Physical pack & capability implementation projects
Artwork, approval & pack cut-over implementations

SECTION 7 - THE END RESULT

VISUALISATIONS OF HOW YOUR PRODUCT MAY LOOK POST FMD IMPLEMENTATION.



ADDITIONAL HELP & ABOUT THE AUTHORS

Stephen McIndoe
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Since 1999, Stephen has helped many pharma and biotech companies and their supply chain partners to define and implement end-to-end serialisation capabilities to both meet legislative requirements and deliver other business benefits.

Stephen heads the serialisation practice at Be4ward, managing a group of specialists offering independent advice through a combination of deep subject matter expertise and excellent consulting skills.

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Stephen Marshman
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Stephen has twenty years' experience in the artwork and packaging sector and today his main focus is helping pharmaceutical companies implement best practice artwork processes.

Stephen played a pioneering role in the development of Schawk's unique approach to working with pharmaceutical clients more than fifteen years ago and remains a key part of the global team today.

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Chris Howells
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Chris has 25 years in the pharmaceutical industry. This includes various technical and operational roles from development site director to packaging manager. For the past two years, Chris has been leading Patheon's serialization efforts.

He holds degrees in Chemical Engineering, Biomedical Engineering, and Project Management.

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ABOUT THE AUTHORS

Be4ward has helped many pharma and biotech companies and their supply chain partners to define and implement end-to-end serialisation capabilities to both meet legislative requirements and deliver other business benefits. We also specialize in the areas of labeling and artwork.

We deliver value to our clients through a combination of deep subject matter expertise and excellent consulting skills.

Be4ward's serialisation services include:
- Strategy development
- Ongoing legislation understanding and impact assessment
- Requirements development
- Independent solution supplier selection
- Detailed design
- Supply chain partner integration management
- Implementation support
- Validation services
- Support model design and implementation
- Project and program management

Schawk is part of the SGK group, the largest independent branding and graphics services provider in the world.

Today our focus encompasses more than simply ensuring our client's and their patients have compliant labeling and packaging. We are working within the sector to help Pharma companies optimize their packaging in order to meet the myriad challenges and opportunities across the ever-changing healthcare landscape, from anti-counterfeiting and serialization to personalized medicine and patient adherence.

Patheon is a leading global provider of pharmaceutical development and manufacturing services.

With approximately 9,100 employees and contractors worldwide, Patheon provides a comprehensive, integrated and highly customizable set of solutions to help customers of all sizes satisfy complex development and manufacturing needs at any stage of the pharmaceutical development cycle.