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Implementation of serialization – AbbVie experience

30th March 2017

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Agenda today

- Background
- Core team
- SharePoint site
- Readiness
- Challenges Affiliates
- Best practice

Why are we doing FMD?

Patient safety and compliance:
Falsified medicinal products are a serious threat to the health and safety of patients around the world. They range from drugs with no active ingredients to those with dangerous impurities. They can be copies of branded drugs, generic drugs or over-the-counter drugs.

Patient health and safety is of the utmost importance to the pharmaceutical industry.
Protecting our patients, our people, our brand and our supply chain is one of our main goals.

Legal Requirements – why we must do it

EU Falsified Medicines Directive 2011/62/EU (*EU FMD of June 2011*) introduces **obligatory 'safety features'** (a **unique identifier** and **an anti-tampering device**) as part of the outer packaging of prescription medicinal products;

Delegated Regulation EU Safety Features publication 9 February 2016

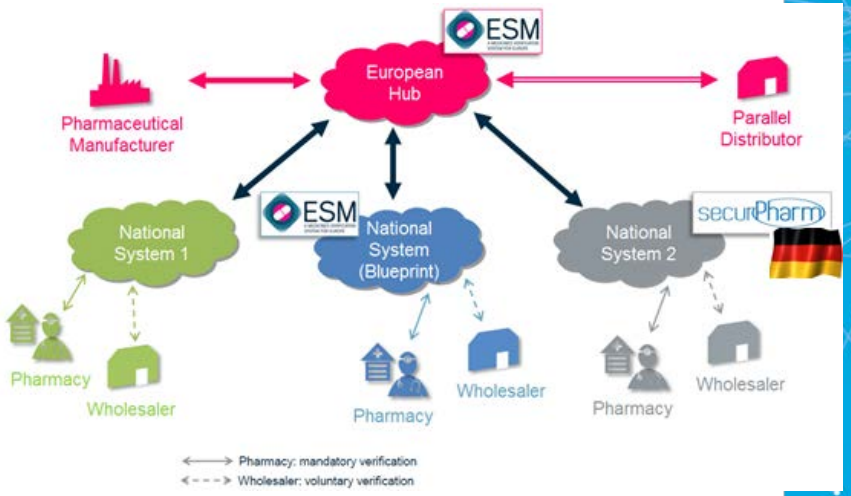
- Implementation: + 3 years = 9 February 2019
- Waiver countries have additional +3 years/2022 (Italy, Greece, Belgium)

EU Safety Features required at saleable unit:

- Anti-Tampering Device (ATD)
- Unique Identifier (UI), utilizing 2D-Matrix barcode

Pan European Verification System

- Interoperable
- Cost-Effective
- Blueprint Systems



Area Core Team AbbVie

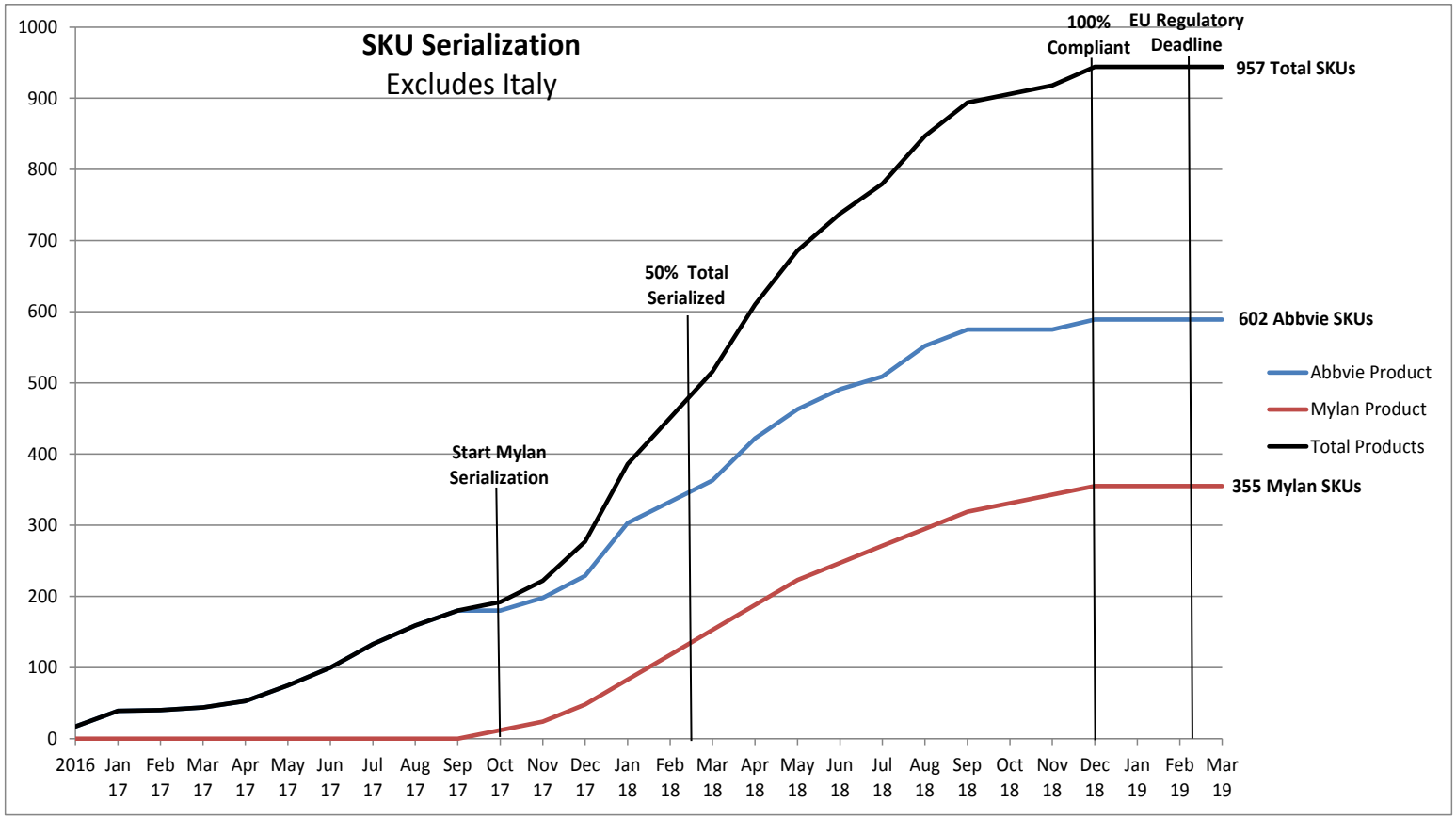
Quality Assurance (QA)	Gert-Jan van Diest (EU Safety Features Program Manager)
Governmental Affairs (GA)	Ludovic Lacaine & Florentin Scarlat
Area Regulatory Affairs (RA)	Ingela Frick, Marika Sebre
Regulatory Affairs (RA)	Lynsey Flitton, Viktoria Grahnen
Business Intelligence (BI)	Vasilis Zormpaidis (LEx Roadmap)
Finance (Fin.)	Marine Hoang-Haas
Label Mgmt. (GLM)	Georgina Gal
Legal / General Counsel	Miguel Esteban
Supply Chain IT	René Kronenburg
Distribution (D&L)	Damien Gannon
Communication	Maureen Goudriaan

EU Program SharePoint

- Share Best Practices
- Template documents & presentation material
- Store project deliverables and other important program info
- Communication
- Share latest news

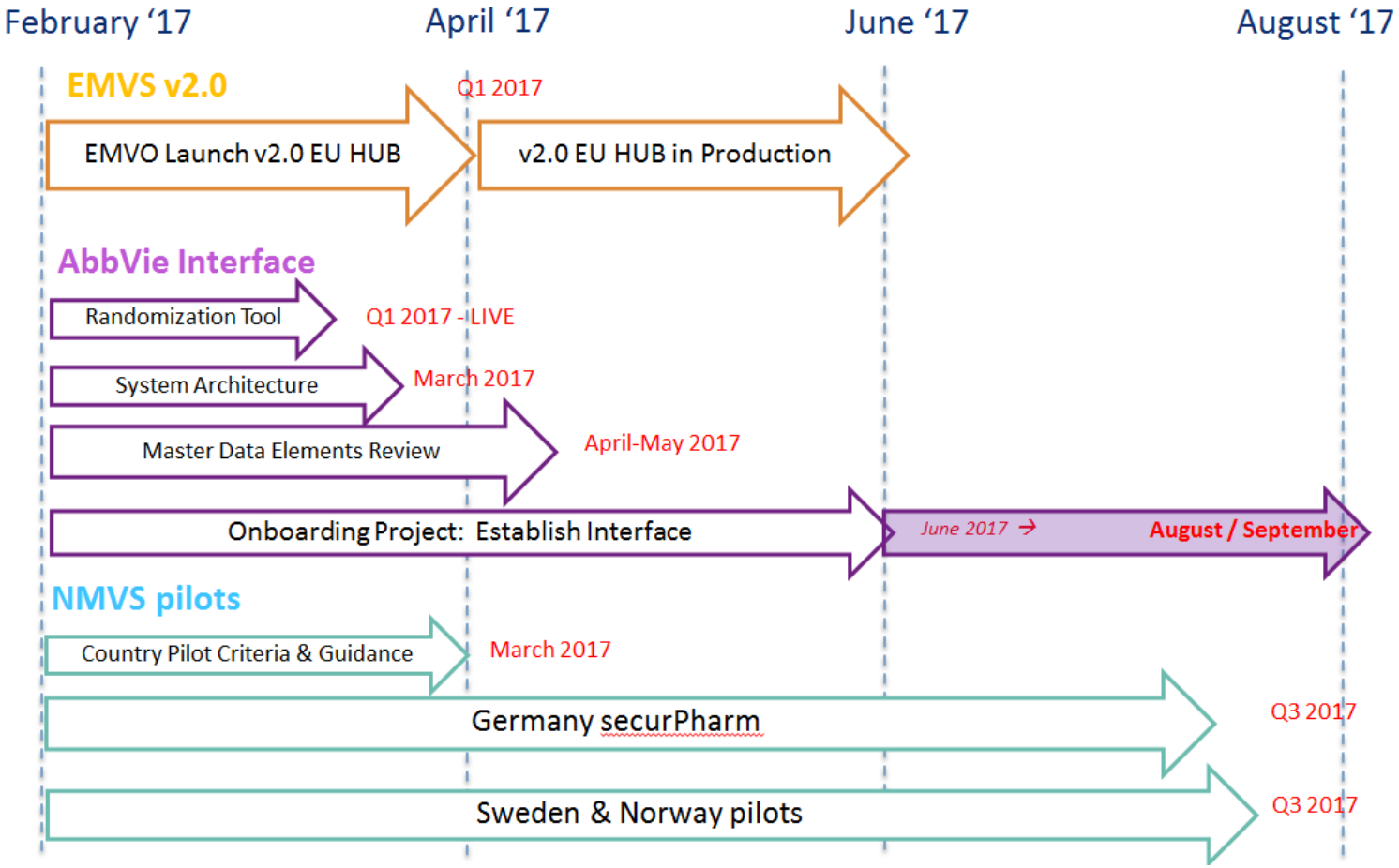
Manufacturing Site readiness

- Serialization
- Tamper Evidence Features



IT Readiness

AbbVie Onboarding Project - Timelines



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Regulatory Readiness

- Centralized products submission guidance, mock-ups
- National product submission guidance and timelines
- Artwork/labeling change management
- Shared Label Strategy (multi-market packs)
- Coding requirements (single GTIN standard vs National Codes)
- Prefixes and Human Readable Information standards
- Phase out of the linear barcode

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Quality Systems Readiness

- Batch release process for serialized products, role of the QP?
- GDP processes to adjust to serialization
- IT validation required
- Role of the 3PL (Affiliate warehouse, distributor)?
- (Suspect) falsified medicines incidents
- Managing Transition Period 2019 - 2025

Organizational Readiness

- Timelines → less than 500 working days left

- Resources and Budget
  - Cross-functional teams
  - All departments impacted
- Master Data Management
  - IDMP
- Communication and awareness
- Legal aspects (OBP, EMVO, NMVO, NTA, MAH)
- Financial aspects:
  - Ramp-Up phase budget 2017-2018
  - Flat-fee cost model >2019
  - Contributions vs Loans

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Challenges Affiliates

- Still lack of blueprint selection
- Still no NMVO set up
- Still no country decision to use GTIN or NTIN
- Need clarification on when lines will be ready
- Need clarification on when mock-ups will be ready
- Wants to understand if they can be allowed to join a local pilot
- Majority needs to understand why a Stake holder mapping is needed and how to do one
- Many affiliates need to market themselves and get a stronger sponsorship
- Need to understand FMD better

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Best practice

- Oversight / transparency of the line-readiness
- TE guidance early on
- Label centre early involvement to plan work-load
- National Products – need for changing packaging material due to adding serialization and TE?
- Possibility of flexible resources to raise & approve artwork changes
- Packaging engineering group and Artwork groups close alignment and collaboration.
- Prepare for the increased workload if monthly numbers increase due to delay in implementation (Dashboard)
- Close collaboration and transparency with Upper Management and/or Steering committee
- Involvement from Commercial early on – advocates and usually the ones who pays

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