B. BRAUN TRACK AND TRACE INITIATIVES
AFRICAN GS1 HEALTHCARE CONFERENCE
Collins Agoro
Addis Ababa, Ethiopia
Introduction

Name: Collins Agoro

Title: Project engineering manager, Serialization & Traceability

Company: B. Braun Melsungen AG, Germany

Role: Traceability law implementation EU, Asia, Middle East & Africa
AGENDA

1. Company Information
2. Motivation
3. Legal requirements
4. Case study (EU-FMD)
5. Conclusion
COMPANY INFORMATION

B. BRAUN MELSUNGEN AG
We stand for these values.

**Innovation**
We create innovations by exchanging knowledge with the users of our products and let this knowledge flow into the development process.

**Efficiency**
We use modern technologies and help hospitals with our innovative products and services to improve their process efficiency.

**Sustainability**
We live sustainability through our commitment to people, the environment and different cultures – in each region in which we are operating.
We have subsidiaries in 64 countries.
Our customers value the benefits provided by B. Braun.

We produce more than 5,000 products and 120,000 articles.
B. BRAUN AT A GLANCE

SALES
6,788.9

EMPLOYEES
61,583

INVESTMENTS
969.2 EUR million

COUNTRIES
64

CORPORATE SOCIAL RESPONSIBILITY PROJECTS
239

RESEARCH AND DEVELOPMENT ACTIVITIES
352.0 EUR million
MOTIVATION

WHY IS TRACK & TRACE NECESSARY?
One of these medicines is fake…..

Can you tell which?

UNPREDICTABILITY
Are counterfeited drugs produced under GMP conditions?

→ NO

RISK
Trading with counterfeited drugs: a profitable business
LEGAL REQUIREMENTS
DEVELOPMENT OF TRACK & TRACE LEGISLATIONS
Overview of main T&T legislations and deadlines affecting B. Braun

USA (11/18)  
EU (02/19)  
Turkey (effective)  
Russia (02/20)  
MENA (tbd)  
S. Arabia (effective)  
China (effective)  
S. Korea (07/16)*  
Brazil (2020ff)

HOTSPOTS  
• Europe (2019)  
• Russia (2020)  
• China (2020)  
• MEA region (2019…)  
• US (2019…)  
• Brazil (2020…)

The affected countries in Europe  
• 28 EU Member States  
• 3 EEA countries (NOR, ICE, LS)  
• Italy & Greece have 3 more years to implement
T&T at B. Braun

3 DIVISIONS
- Hospital Care
- Homecare
- Dialysis

DEPARTMENTS
- ALL

EU-COUNTRIES INVOLVED
- ALL

ARTICLES AFFECTED IN EUROPE
- Prescription / Black list

PRODUCTION SITES
- > 13

LINES
- > 45

B. Braun Melsungen AG
CASE STUDY
THE EUROPEAN FALSIFIED MEDICINES DIRECTIVE (EU 161/2016)
Overview of EU-Falsified medicine directive

Protecting patients from falsified medicines in the legal supply chain – FMD 2011/62/EU

- **2011**: July 2011 Publication of FMD
- **2013**: Jan 2013 Publication of FMD
- **2015**: Q3 2015 Adaptation of delegated acts
- **2016**: Q1 2016 (?) Publication of delegated acts

36 Months

Non compliance puts sales at risk
T&T EU FMD – the „End-to-end“ verification system

SAFETY FEATURES
1. Serialization of packs with (UI) unique identifier
2. Anti-tampering device (ATD)

REPORTING
3. Upload and maintain status of (UI) in the EU HUB
B. Braun T&T architectural strategy

Level 5: External Stakeholders

Level 4: Global Enterprise Level
- CMS
- ERP
- SAP ATTP

Level 3: Local Site Level
- Site Manager
- Print Center
- Printer

Level 2: Local Line Level
- Line Controller
- Line Controller
- Line Controller

Level 1: Local Devices Level
- Printer

Production:
- Line 1
- Line 2
- Line 3

Offline Rework
- Process Order Data
- Serialisation / Aggregation
- Rework
- Reporting / Warehouse

Serialization / Track & Trace

EU HUB
30x NMVO’s

Serialization / Aggregation
Track & Trace
Verification / Authentication
EMVO: EU-HUB Onboarding

**Administrative onboarding**

- Step 1: Provide initial information  
  Complete
- Step 2: Non-disclosure agreement  
  Complete
- Step 3: Detailed information and participation agreement  
  Complete
- Step 4: Approvals
- Step 5: Technical onboarding

**Technical onboarding**

- EU HUB
- B. Braun Melsungen AG  
  ✓
- B. Braun MAH ecosystem
- Germany

Main MAH (Onboarding Partner)
National medicine verification organisation

Onboarding workflow

- Contract Released
- Legal Review
- Contract Signed
- One time Fee-Paid
- Technical Connection

National System

European Hub

Pharmacy

Wholesaler
Challenges of EU-FMD implementation

- Time (Onboarding)
  - Administrative
  - Stakeholders coordination

- Inadequate Resources
  - Few Experts
  - Heavy financial expectations

- 30 contractual agreements
  - Review Contracts
  - Effort in Training.

- Challenging IT environment
  - Creating Harmonization
  - MAH Onboarding

- Wholesalers NMVS connection
  - Huge Task (17 Connections)
  - Implementing Harmonization
Conclusion-Interconnectivity is the key
THANKS FOR YOUR TIME
BE ON TRACK!