Implementation of FMD in Bulgaria
Establishment of BgMVO

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FMD is about …

- Patient Safety
  - Delivering patient confidence in medicines
  - Protecting patients against counterfeit products

- Regulatory Compliance
  - Ensuring compliance deadlines defined by regulators and governments are met

- Supply Chain Security
  - Improving visibility and efficiency across the supply chain

- Value Through Standardisation
  - Working with GS1 to optimise the way healthcare is delivered globally
  - Defining standard processes, solutions and equipment for GMS to maximise investment and control complexity
The Impact of Counterfeit

- In some developing areas of Asia, Africa and Latin America up-to 30% counterfeit sales
- 50% of illegal sales on the internet
- Recent study of EUIPO shows 4.4% counterfeit-medicines sales in Europe (this means 440 million packs per year)
Can you tell the difference

- According to Interpol more than 1 million people die each year from counterfeit drugs
- The mortality of HIV/AIDS in 2015 was 1.1 million people (WHO, The Top 10 causes of death, Jan. 2017)
- Road injuries killed 1.3 million people in 2015 and this is the 10th leading cause of death (WHO, The Top 10 causes of death, Jan. 2017)
Falsifiers do not spend money on GMP, but invest in packaging equipment.

**Profits:** 500 times higher than investments.
BgMVO Vision in the Memorandum of Understanding signed July 2015

• **Model**
  - Mandatory decommissioning at the point of dispense
  - Verification on receiving Rx in the pharmacy
  - GTIN coding with the 2D code
  - Rx products according to the FMD, tender Vx verification at WH

• **Governance**
  - Non profit organisation of 5 stakeholders
  - Equal rights of all stakeholders, full consent for important issues
  - Flat fee principle (equal membership fees and verification fees)
  - Collaboration and consultations with Authorities (BDA, MoH)

• **System**
  - Single pan European system
  - Blueprint model to be followed
  - Support to local Onboarding Partners

• **Benefits**
  - Meets all requirements of the Directive
  - Minimised complexity
  - Cost efficiency
  - Foundation for other functionalities
Concept: point of dispense verification

Verification on receiving Rx and decommissioning on dispensing to patients
Coding recommendations: GTIN and 4 elements

Data Matrix – Coding proposal derived from GS1 standards
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

- Manufacturer Product Code (GTIN) 14 digits
- Unique Serial Number (randomized) up to 20 alpha-numeric characters
- Expiry Date (in Bulgarian) 6 digits (YYMMDD)
- Batch Number (in Bulgarian) up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

PC: GTIN (01) 07046261398572
Парт. №: (10) TEST5632
Годен до: (17) 23021
S/N: (21) 19067811811
EMVO constituency members
BgMVO members match the EMVO constituency members
The blueprint model: a standardised national system with all necessary functionality
Flat Fee Model: annual costs for full operation

- **Hub cost**: Share of BG is 1-2 % EU Hub, size 3 < 5 % of total costs of the NMVS
- **NMVO cost**: Governance and local system costs < 30 % of total costs
- **System cost**: Costs of NMVS to service providers > 65 % of BG costs

**Total**: 2,500 k€ > Budget > 1,500 k€

- Flat fee model (# MAH)
- **Annual fee per MAH**: < 15 k€
Implementation of the FMD in Bulgaria

- July 2011: Publication of FMD
- Dec 2012: Changes in BG Drug Law
- July 2015: Memorandum signed
- April 2016: BgMVO registered*
- April 2017: BSP selected
- Sept 2017: Pilot start
- Q3 2018: Ramp-up start
- 9 Feb 2019: Mandatory Authentication

36 Months
Priorities of BgMVO in 2017/2018

• **System:**
  – Selection of IT provider Q2/2017
  – Cooperation with GS1 Bulgaria about Product Code (GTIN)
  – Support to local Onboarding Partners
  – Engagement of local IT providers
  – Pilot phase in Q4/2017 and Ramp-up in Q3/2018

• **Governance:**
  – BgMVO incorporation
  – Office organisation
  – Funding of the organisation: local contracts; verification fees
  – Staff, roles and responsibilities
  – QMS and SOPs for the office and for the verification system

• **Communications:**
  – Meetings with authorities: implementation of safety features
  – Training of pharmacists
  – Positive PR campaign to the public in Q4/2018
  – Drafts of local legislation in consultations with authorities
THANK YOU

Q&A