Fighting Falsified Medicines in Europe: EMVS – How Manufacturers Make the Difference

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AGENDA

FMD & DR

Hub & Blueprint: Harmonisation, Interoperability & Cost Effectiveness

Flat Fee Approach: Transparency & Fairness

NMVO Governance: Inclusive & Balanced
Falsified Medicines Directive & Delegated Regulation

- FMD Art. 54a (2)(e): The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.
- DR Art. 31 (1-3):
  - The repositories system …shall be set up and managed by….manufacturers and marketing authorisation holders of medicinal products bearing the safety features.
  - In setting up the repositories system, the legal entity or entities referred to in paragraph 1 shall consult at least wholesalers, persons authorised or entitled to supply medicinal products to the public and relevant national competent authorities.
  - Wholesalers and persons authorised or entitled to supply medicinal products to the public are entitled to participate in the legal entity or entities referred to in paragraph 1, on a voluntary basis, at no cost.

EMVO stakeholders have a common vision of medicines verification

Main deliverables for Manufacturers:
Set up a stakeholder-governed model that is
- Save
- Harmonised
- Cost-effective
- Inter-operable
- Transparent
The European Hub is reality and its value undisputed

- Safety (cloud based, EDQM)
- Secures cross-border trade
- Ensures interoperability between national systems
- Supports establishment of standard interfaces
- Provides cost savings for connecting manufacturers
Pan-European architecture: The „National Blueprint System“ approach

A Blueprint system is a lot more than standardised software

Main elements

- Implementation of national systems based on a common standard, i.e. compliance with URS
- Support for national stakeholders by EMVO during deployment process (to be paid for by national stakeholders)
- Management by EMVO on behalf of the respective national stakeholders (paid by them)
- Technical operation by a limited number of IT providers
The Blueprint approach provides substantial benefits

**Expected Benefits**

- De-facto standard for implementation of national systems
- Complexity reduction for NMVOs
  - During deployment (support by EMVO)
  - During operation (management by EMVO)
- Cost reduction for MAHs through economy of scale
  - During deployment (procurement of ‘many’ national systems from one single IT provider - 3 IT providers to chose from )
  - During operation (management of ‘many’ systems by EMVO)
  - High savings potential
- Benchmark for Total Cost of Ownership
- National adaptation for specificities possible
- National choice of IT provider within the framework

**Common Concepts and Standards:**

**Unique Identifier**

- Data-Matrix code, developed to ISO-standards
- Key data elements:
  - Product code (GTIN/NTIN)
  - Randomised unique serial number
  - Expiry date
  - Batch number
  - National health number (where necessary)

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890

Mandated by Delegated Regulation
Cost allocation model: Conclusion on a flat fee model

- **Practicality**
  - Easy way of calculating: equal division amongst MAHs and PD
- **Fairness**
  - Takes into account market activity: companies with multiple MAHs pay more
- **Transparency**
  - Simple accountancy / audit
- **Predictability**
  - Calculations based on number of active participants in the market the year before the fee adjustment
- **Balanced**
  - A company can be more active in country A, compared to country B and will therefore pay more in country A
- **Upfront payment**
  - In order to prevent free-riders, easy calculation gives opportunity to pay upfront
Invoicing principles

Share of Hub cost: as per market size
Share of total cost: as per market specific flat fee

Manufacturer AH ≠ Marketing AH

By virtue of Article 54a (2)e, the costs of the repositories system shall be borne by the Manufacturing Authorisation Holders.

- Manufacturing AH do not operate directly on the markets that their products serve unless they are also the Marketing AH.
- Legitimate connection to Hub only for Marketing AH (protection against unauthorized and uncontrollable data upload, responsibility on the Marketing AH for the proper implementation of the EMVS).
- Manufacturer AH ≠ Marketing AH: contractual agreement in order to regulate that EMVS fees to be paid by Marketing AH and the terms on which those costs may be passed on to the relevant Manufacturing AH.
AGENDA

1. FMD & DR
3. Flat Fee Approach: Transparency & Fairness
4. NMVO Governance: Inclusive and Balanced

EMVO members are allocated to a constituency

To be mirrored nationally!
Fair & Balanced Representation

- 5 constituencies occupied by local associations or individual stakeholders. In the constituencies, the 5 stakeholders should be represented, however only once (3:2)
- If different national landscape: **fair and balanced** division of voting rights between associations/constituencies of MAH, wholesaler & pharmacists
- Decisions should be taken on a consensus basis.
- Decisions based upon or according to majority of voting rights should be avoided by principle.  
  **Rule: Wholesaler & pharmacists to be ready to pay participation in governance cost.**

Questions?