The role of the European Commission during the FMD implementation phase

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Delegated Regulation on the Safety Features

Adoption phase

The delegated Regulation (EU) 2016/161 "laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use":

- **Was adopted** on 2 October 2015;
- **Was published** in the Official Journal on 9th February 2016;
- **It applies as of 9th February 2019** in all MS

DR aims at addressing the problem of falsified medicines in the legal supply chain and improves the traceability of medicines by establishing Union-wide rules for the implementation of SF
Delegated Regulation on the Safety Features

*Implementation phase*

- Implementation is based on a **stakeholder model**:
  - Repository system shall be set up and managed by MAH/MIAH
  - Costs of the repository system shall be borne by the MIAH

- Commission and MS have a significant role in **facilitating the implementation**
  - Regular meetings and exchange of experience of the EG are of high importance
What are the key deliverables and timelines for SF implementation?

- **Feb 2016**: NMVOs set up
- **Aug 2016**: IT providers identified
- **Dec 2016**: National repositories set up
- **Feb 2017**: On-boarding of repositories users
- **Feb 2018**: System testing/training phase
- **Aug 2018**: 
- **Feb 2019**: 

**Timeline:**
- Feb 2016
- Aug 2016
- Feb 2016
- Aug 2017
- Feb 2018
- Aug 2018
- Feb 2019
What are the key deliverables and timelines for SF implementation?

- **Aug 2016** – set up of NMVOs
- **Dec 2016** – decision on IT providers to run the national repositories
- **Aug 2017** – national repositories established
- **Aug 2018/Feb 2019** - testing of the repositories system/training phase
- **Feb 2019** – the repositories system is fully functional and used for medicine verification across the EU
Activities during the implementation phase

- Commission is committed to continue organising *expert group meetings* to facilitate a harmonised implementation of the DR
- 4 *MS working groups* have been set up on specific technical topics for which a harmonised approach is of crucial importance

1. Supervision of repositories (Lead: IE)
2. NCA access to repository system (Lead: ES)
3. Data traceability (Lead: IT)
4. Exchange of best practices (Lead: BE)
Outcome of the expert group on 12 December 2016 (1/4)

- Progress of national repositories system
  - **Progress** in setting up the NMVO, most of them pre-selected IT provider, contract planned for first quarter 2017
  - Most Member States confirmed the involvement of all stakeholders including hospitals/pharmacists
  - No major obstacles but reporting of issues related to the cost allocation model (e.g. SME)
  - National repository system and interest in supranational system (BE-L; Malta interest to approach UK, IE; Greece-Cyprus)
Outcome of the expert group on 12 December 2016 (2/4)

- Progress of national repositories system
  - Extension of use of the safety features
    - **UI:** some MS to consider for reimbursement purpose
    - **ATD:** most of Member States consider voluntary use (e.g. if in place to retain), some MS to extend to all OTC
Outcome of the expert group on 12 December 2016 (3/4)

- Outcome of the questions from stakeholders

  - Called MS to **populate the Eudra GMDP database**
  - **Aggregation**: openness in the DR, to be decided by the stakeholders, question on implementation, possibility to give interpretation in the question and answer document
  - **Multi market pack**: raised attention to MS to avoid legal obligation to have NN in the 2D barcode
  - **Voluntary use** of the SF
Outcome of the expert group on 12 December 2016 (4/4)

• Questions raised by the Member States

  • Can EMVO/NMVO suspend the access to the repository for non payment of fees
  • Who will pay in the implementation phase until February 2019
  • Can the information be uploaded directly to the national repository (Art. 33.3 data to be uploaded to hub or NMVS)
  • What kind of data will be available from the repository system?
Thank you for your attention!