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

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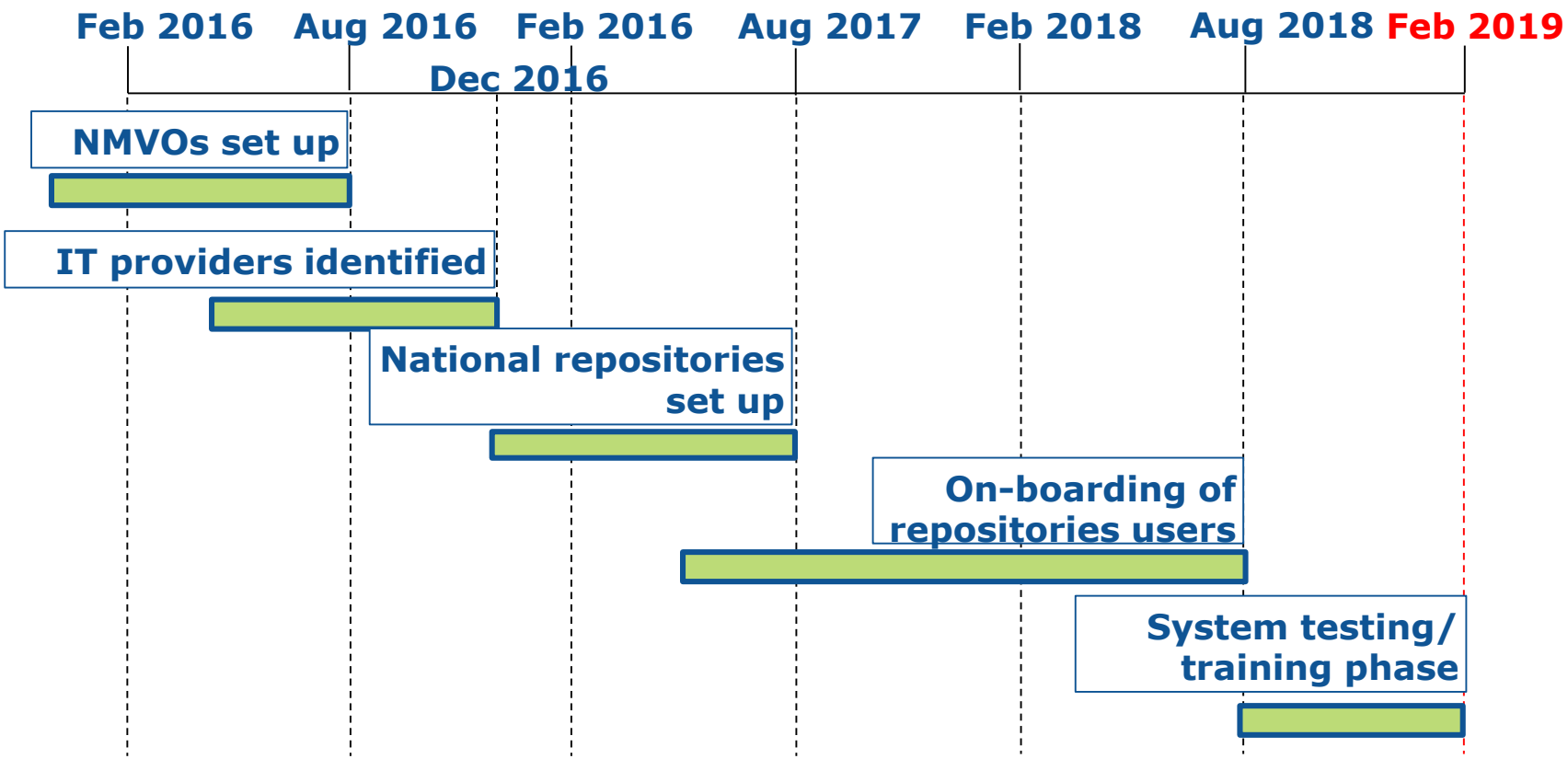
Delegated Regulation on the Safety Features
Implementation phase

- 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?



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**: openess 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?

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Thank you for your attention!

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