Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

News from Fimea

16.11.2017

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Near future

- Fimea to be well-equipped for future challenges (e.g. Brexit) new organisation started 1.1.2018
- Business as usual, but responding to possible resource needs
- MAHs should prepare for changes asap to on time with the requirements of Safety Features by 9.2.2019

EU Commission's Delegated Act 2016/161

- Published on 9.2.2016

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2016_032_R_0001&from=EN

- EC has informed that **there will be no variations** to the delegated act **before 2019**

-> **Authority expectations is to have the systems set up and running as required by 9.2.2019**

Information available on EC website

- Q & A, new versions added regularly, current v.8:

https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v8_0.pdf

Please refer primarily to this information -> aspirations is to have as harmonized approach in MSs as possible

- Next version (v. 9) to be published soon, possibly on **9.2.2018**

Answers to a number of questions posed by stakeholders to EC and NCAs, hopefully e.g answers to some complexity drivers

Information available nationally

- **Information about requirements** to MAHs also on website, e.g:

FI:

http://www.fimea.fi/myyntiluvat/laakkeiden-turvaominaisuudet

* Information in English, please go through main page www.fimea.fi and choose language EN→ marketing authorisations-> Safety Features

Introduction of a unique identifier on the package label

- The package labelling can be updated in connection with a variation application that concerns the product information, or as part of a renewal of a marketing authorisation for a medicinal product or as a separate 90-day notification (Notification pursuant to Article 61(3)) in accordance with the CMDh implementation plan.
- http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Falsified_Medicines/CMDh_345_2016_Rev00_02_2016_1.pdf

Marketing authorisations approved via MRP or DCP (UI to packaging information)

- The harmonised QRD-texts should be updated by an application submitted via a common mutual recognition procedure in accordance with the CMDh implementation plan.

- The mock-ups may be updated in connection with this application or the changes may be implemented on the mock-ups later so that the packages contain the unique identifier in accordance with the Commission Delegated Regulation (EU) 2016/161 by 9.2.2019.

Marketing authorisations approved via national procedure, UI to packages

- Unique identifier (2D-barcode and human readable format) are added directly to mock-ups
- The QRD-texts are not updated.

All marketing authorisations

- **The unique identifier may be added on the mock-ups without a separate 90-day notification when the following conditions are fulfilled:**
- The 2D-code and the human readable information (or 2D-code only if the package is sufficiently small) is not positioned on the front of the package.
- Existing text on the side panel where the above information is located may be removed on the condition that it is already printed on another panel on the package or if it is included in the human readable information of the 2D-code (such as batch, expiry date). Texts should not be moved.
- The font size of existing information text must not be changed.
- Existing texts, images and/or layout is not moved or modified..

Introduction of an anti-tampering device (ATD) on the package

- The anti-tampering device (ATD) may be placed on the outer packaging without a separate notification when the addition does not affect the layout of the label.
- When the addition of the ATD changes the layout of the label, the mock-ups should be submitted to Fimea via a 90-day notification.
- When the ATD is placed on the immediate packaging of the medicinal product, the information should be updated in the quality part of the dossier (Module 3, 3.2.P.2.4 and 3.2.P.7) submitted as a type B.II.e.1 variation application in accordance with the CMDh implementation plan.
- The ATD may be placed also on the packaging of the medicinal products **without a prescription**; however, for them the **applicant should send Fimea an e-mail notification** to address mrp@fimea.fi, with a subject “Anti-tampering device” including other product information.

Legislation changes

- No definite timetable set at this point
- Possible first suggestions after summer 2018
- Fimea's administrative regulations will be revised concomitantly with possible changes in the Medicines Act
- Hearing phases possible once mandate known in the Medicines Act

FiMVO to be contacted to get on-board

- Finnish Medicines Verification Organisation (FiMVO) is formed by the stakeholders, Fimea does not participate
- **Please refer to FiMVO for practical information**
- MAHs should **contact both** EMVO (European Medicines Verification Organization) for HUB on-boarding **and**

  FiMVO for local for contracting

NCAs inspecting repository and NMVO

- Mandate to inspect given in Art. 44 of the Delegated Act
- Right to inspect starts formally from 9.2.2019, no obligation before that to inspect; some NCAs may wish to conduct pilot activity
- EMVO also auditing NMVOs
- NCAs required to report inspection results to EMA
- Harmonized inspecting procedures

  Expert Group on Safety Features

  - Sub-Group 1 Supervision of Repositories
- Possible delegation of obligation to another NCA or to a third party (written agreement)
- Licensed stakeholders (incl. IT-systems) also under supervision.

Opportunities and challenges

- Opportunities:
  - Tightened supervision of falsification cases
  - Speedy information flows of reporting to stop falsified medicinal products spreading across EU -> audit trail needed
  - Even closer co-operation between NCAs
- Challenges:
  - No time to waste: only 12 months to go!
  - Possible shortages, if manufacturers/MAHs are not on time

Thank you!