FiMVO
Finnish Medicines Verification

WELCOME TO FIMVO NEWSLETTER!

As the year 2024 is coming to its end, it is also time for this year's last newsletter.

In this newsletter:

EMVO: MASTER DATA GUIDE – NEW VERSION IS NOW AVAILABLE

EMVO has shared the newly revised Master Data Guide, designed to provide clearer guidance and an improved flow of information.

You can find the document on our website and also on EMVO's website under the Knowledge Database -> Documents Overview -> On-boarding Partner (OBP).

DEPLOYMENT OF THE EU HUB RELEASE 1.16 IN THE PRODUCTION ENVIRONMENT

Please note that following the successful results of the Interoperability Test (IOT), EMVO can confirm the official deployment date of the EU Hub Release 1.16 in the production environment:

- The deployment will begin at approx. 08:00 CET on **25 January 2025**
- Release 1.16 will be ready for use in PRD at approx. 23:00 CET on 25 January 2025
- **There is a downtime window starting at approx. 09:00 CET on 25 January and ending at approx. 23:00 CET on 25 January.**

We would like to remind you that additional existing fields in the Product Master Data (PMD) and Product Pack Data (PPD) will be made mandatory with the deployment of the EU Hub Release 1.16. Consequently, in case you fail to fill in properly the indicated mandatory fields (as of 25 January 2025), you will be unable to upload the data to the EU Hub. Please refer to Version 4 of the Q&A Document on "PMD Introduction of additional mandatory fields" to find out more about the actions which you need to take.

Please note that uploading the required information into the EU Hub before the medicinal product is released for sale or distribution, is a requirement set out in the Commission Delegated Regulation (EU) 2016/161 (see Art 33).

If you have any questions, please do not hesitate to contact EMVO's Helpdesk: helpdesk@emvo-medicines.eu.

LAST CALL FOR PO NUMBERS FOR 2025

If you haven't yet sent FiMVO your PO number for the 2025 annual fee, please send it as soon as possible to info@fimvo.fi. The annual fee is 4400 € / MAH. You'll receive the invoice in the first week of January and the due date will be at the beginning of February.

If your invoicing address has changed since last year and you haven't informed us about it, please let us know by filling Appendix I and II fully and sending it back to us by

email to info@fimvo.fi.

NIXIT (NORTHERN IRELAND EXIT): UKNI WILL BE DISCONNECTED FROM THE EMVS 1ST OF JANUARY 2025

UKNI will be disconnected from the EMVS on 01 January 2025. This change will require actions from OBPs having products with "GB" as one of the designated markets. We have summarized the main points in our news article.

Read the news article here

PRODUCTS AND BATCHES NOT IN SCOPE OF THE FALSIFIED MEDICINES DIRECTIVE (FMD)

There are some products and batches in the Finnish supply chain having a 2D matrix printed on packs even though not falling under the scope of the Falsified Medicines Directive (FMD), e.g. non-EU batches and medical devices. Scanning these packs causes unnecessary errors in the National Medicines Verification System (NMVS).

There is a functionality in the NMVS that allows the creation and maintenance of a list of products and batches not in scope of FMD (so called non-FMD list). To minimize the number of unnecessary errors, a product and batch may be added to the list based on a case-by-case risk assessment.

Finnish Medicines Verification Organisation FiMVO maintains the content of this list in the Finnish Medicines Verification System (FiMVS) under the supervision of the Finnish Medicines Agency Fimea.

We have summarized the main points in our news article.

Read the news article here

RECALL AND WITHDRAWAL IN EMVS – NORDIC RECOMMENDATIONS

The Nordic NMVOs provide secure, straightforward and supportive systems for verifying medicines. The system alerts if a falsified medicine should turn up and warns if medicines already dispensed or destroyed are dispensed.

The system can also be used to ensure that packs from recalled batches never reach the patient. This results in additional quality control in the medicine handling process. Together we help to make sure every individual can have confidence in their medicine.

The Nordic NMVOs have recently updated our “Nordic Best Practice” on how to do a Recall or Withdrawal through the EMVS, check it out.

Read the guidance

FIMVO ON CHRISTMAS BREAK 23.12.2024 – 6.1.2025

The FiMVO office is open only with limited resources from December 23rd to January 6th. We provide support regarding urgent issues during the holiday season on business days. Please submit other issues, e.g. contract and invoicing changes well in advance. Please find our contact information at the end of this newsletter.

The FiMVO team wishes you a Merry Christmas and Happy New Year!

Please contact us

- Regarding contracts and invoices: info@fimvo.fi
- Regarding alerts and medicines verification system: nmvs@fimvo.fi

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