







WELCOME TO FIMVO NEWSLETTER

As we mentioned on our last newsletter, this Autumn FiMVO will change the supplier of the verification system. In this newsletter we want to share more information about the change:

- Deployment and downtime in the FI-NMVS production environment starting on November 18th, 2023 at 20:00 CET
- Alert Handling Guidelines have been updated effective from 19.11.2023
- Counterfeit Ozempic products have been found in Europe
- Upcoming invoicing of 2024 Let us know your PO number by the end of November
- Keypoints from MAH Webinar (14th of September)

FIMVO CHANGES SYSTEM SUPPLIER ON NOVEMBER 18TH, 2023: DEPLOYMENT AND DOWNTIME IN THE FINMVS PRODUCTION ENVIRONMENT STARTING AT 20:00 CET

The FiMVS system will be migrated to SSR in the production environment on Saturday, November 18th. The starting time of the cutover and downtime will be at 20:00 CET on Saturday and the expected time of completion is at 08:00 CET on Sunday, November 19th, at the latest.

Please note that no OBP transactions can be made in the Finnish system during this 12-hour period as all connections from FiMVS to the EU HUB are closed.

Read more

FIMVO CHANGES SYSTEM SUPPLIER ON NOVEMBER 18TH, 2023: ALERT HANDLING GUIDELINES HAVE BEEN UPDATED - EFFECTIVE FROM NOVEMBER, 19TH 2023

The changes regarding Solidsoft Reply (SSR) NMVS have been taken into account in our Alert Handling Guidelines. The changes are effective from **November**, **19th 2023 onwards**.

Find the updated Alert Handling Guidelines here

Please note that the embedded guidelines on FiMVS's website will be updated with the new version during November, 20th.

To the Alert Handling Guideline website

COUNTERFEIT OZEMPIC PRODUCTS HAVE BEEN FOUND IN EUROPE

The European Medicines Agency EMA and the Finnish Medicines Agency Fimea (in Finnish) report that counterfeit Ozempic 1 mg products have been detected in the EU and the UK. The counterfeits have been found in the legal distribution chain at pharmaceutical wholesalers. Ozempic counterfeits were detected using the medicines verification system.

Read the article here

UPCOMING INVOICING OF 2024

We will send the invoice for the next year's annual fee on the first weeks of January. If you need a PO number on the invoice, please let us know the PO by the end of November. Fill in the Appendix I and II and send it to us (info@fimvo.fi). Thank you for making the invoicing go smoothly!

The annual fee for 2024 is 5 000 € / MAH

FiMVO does not grant reduced fees

Use this Appendix I and II to inform the PO number

KEYPOINTS FROM MAH WEBINAR

Did you miss the MAH Webinar on 14th of September? You can find the full event recording and material on our website.

Check the material here

Keypoints

- Solidsoft Reply (SSR) has been chosen as the new system supplier: The cutover to SSR NMVS in the production environment (PROD) will happen during Saturday, November 18th (evening / night)
- The change does not require any actions or changes from marketing authorization holders

- It is not possible to perform any OPB transactions in the Finnish NMVS via the EU Hub during the cutover on November 18th; any attempt will end up in error and needs to be re-sent after the cutover
- Most common alert types and root causes in FiMVS are: A68 The batch ID does not match serial Number, A3 Unknown serial number, A7 Property is already set on pack
- When your MAH name, any invoicing or company information changes or when you need to add or delete an MAH: use Appendix I and II (linked above)



As always, you can contact us

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



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