FiMVO
Suomen Lääkevarmennus

WELCOME TO FIMVO NEWSLETTER!

A lot has happened since our last newsletter to you. In this mail we have gathered some important articles for you to read!

In this newsletter:

- A reminder - Batch data not uploaded in the EMVS
- EMVO LoA: Q&A document updated – Clarification to the new Q&A 5.14
- Need to update your knowledge on medicines verification? - Check our training events' materials
- Invoicing for 2023 – FiMVO needs your PO number

A REMINDER - BATCH DATA NOT UPLOADED IN THE EMVS

We would like to remind all MAHs/OBPs of the importance of uploading batch data in the EMVS before releasing the batch for sale or distribution. According to the Finnish Medicines Agency Fimea, the failure to upload the data of a batch released for sale or distribution is considered a product defect and should be handled as such by the MAH. The 2D code printed on the pack and the data uploaded in the EMVS together constitute a part of the labelling of the product. It is the responsibility of the MAH to ensure that the labelling of the product complies with the regulations and the requirements of the MA.

Read the original article

EMVO LOA: Q&A DOCUMENT UPDATED – CLARIFICATION TO THE NEW Q&A 5.14

The European Commission published a new version of the Questions & Answers (Q&A) document on “Safety Features for Medicinal Products for Human Use (V.20)” in June 2022. Question 5.14 and its answer were added to the document.

The answer states that a wholesaler may verify beforehand the authenticity of a pack when it is not in their physical possession, but which the wholesaler is in the process of acquiring. This practice should be considered as an additional check if the wholesaler receives the pack e.g. from outside the EU or from another wholesaler.

Read the whole article

NEED TO UPDATE YOUR KNOWLEDGE ON MEDICINES VERIFICATION? - CHECK OUR TRAINING EVENTS’ MATERIALS

Missed our MAH Training in September? Nothing to worry! On the agenda we had current topics (Next year's MAH fee and invoicing timetable, Most Common Alert Types, National Alert Management System and Tips for MAHs - upload of batch data, PMD: Market and MAH name) and we had a guest speaker, Pharmacist **Tiina Miettinen**, from HUS Apteekki (the Hospital District of Helsinki and Uusimaa) introducing us to Medicines verification from a hospital pharmacy perspective.

Find the MAH Training material here

In addition to biannual MAH Training events, this autumn we organized a Verification Basics for MAHs where we welcomed all who are new to the topic or wanted to refresh their knowledge. In the event, we went over a short introduction, The ABC of medicines verification (How does the EMVS work?, Multi-Market Presentations, Inter-Market Transactions, alerts and advice) and contract and invoice matters (When and how to update the contract?, SPOC change and How FiMVO invoices?)

Check out the material and to keep your knowledge up to date!

INVOICING FOR 2023 – FIMVO NEEDS YOUR PO NUMBER

We are in the midst of preparing next year’s invoicing and would like to inform you on the costs and timetable. The annual fee per MAH will be 5 000 €, the invoices will be dated to 2nd of January and the due date will be 1st of February.

If your company needs a PO number to be mentioned on the invoice, please send it to us by using the Appendix I and II form. Send it back to us fully filled and signed to info@fimvo.fi.

If you have already sent us your PO number or your company doesn't use PO numbers, you can ignore this reminder.

We appreciate your help in making the invoicing process as easy as possible for all of us!

As always, you can contact us

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

FIMVO WISHES HAPPY AND SUNNY AUTUMN!

Suomen Lääkevarmennus Oy
Porkkalankatu 1
00180 Helsinki