FiMVO

Suomen Lääkevarmennus

Medicines Verification – The End of the Soft Launch Workshop for MAHs

05 November 2019

Agenda

13.00 Coffee and welcome!

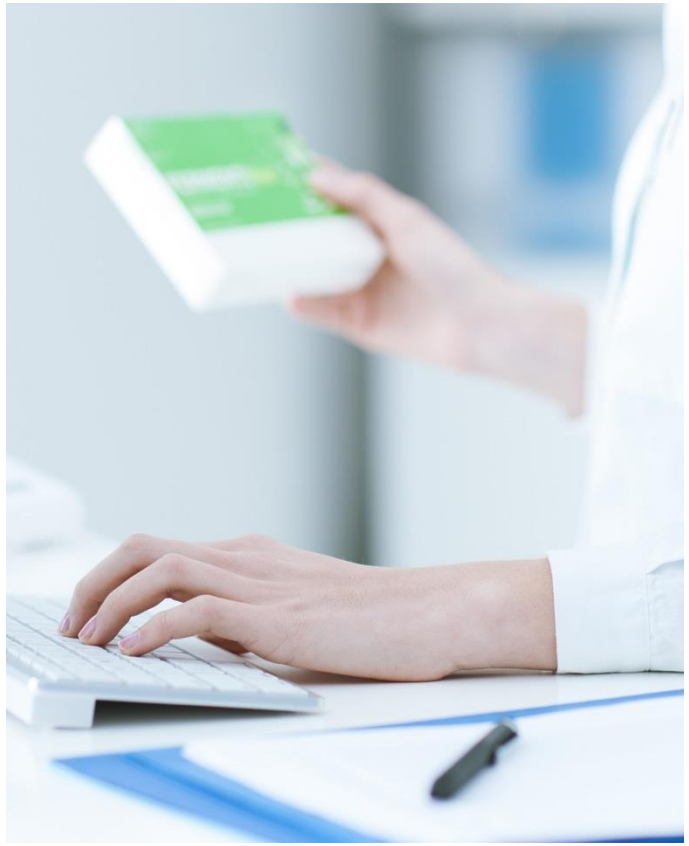
13.10 Where are we with verification

- System status update
- Alerts & approaching the end of soft launch period

Teijo Yrjönen, QA Manager, FiMVO
Mirka Koski, Service Manager, FiVMO

14.10 Q&A

14.45 End of workshop



Where are we with verification

Topics:

- System status update
  a) End users
  b) MAHs, Product Master Data & Batch data

- Alerts & approaching the end of soft launch period
  a) Alerts in general
  b) Statistics on alerts in FiMVS
  c) Approaching the end of soft launch period
  d) EMVO newsletters
  e) Challenges & way forward

Status update

End users created in FiMVS by FiMVO:

- 823 pharmacies/dose dispensers
- 23 hospital pharmacies
- 58 dispensaries
- 6 wholesalers (Magnum Medical, Medapta, Medifon, Oriola, Tamro & Veripalvelu (Blood service))

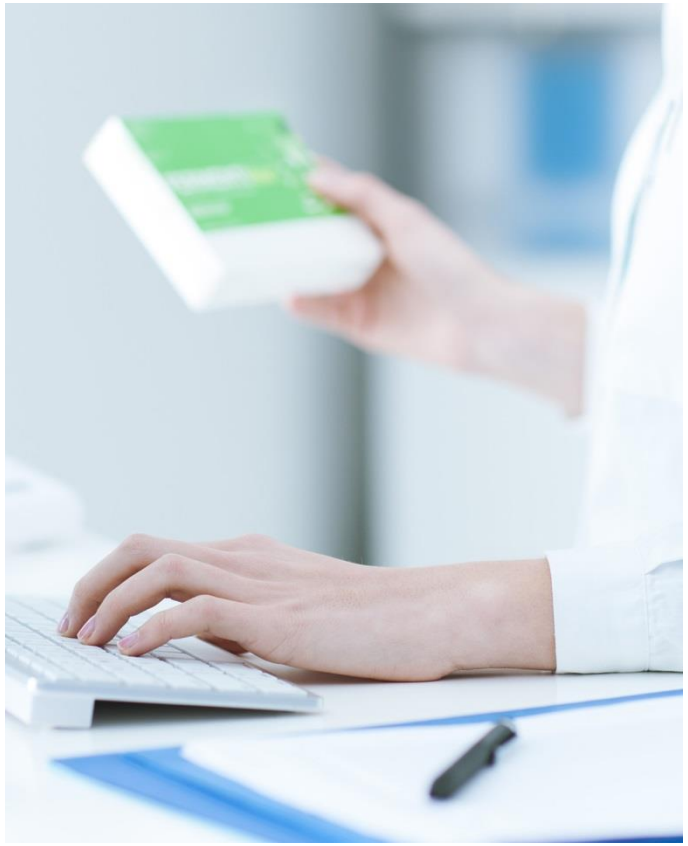
Active users:

- 823 pharmacies
- 23 hospital pharmacies
- 40 dispensaries
- 5 wholesalers

The number of MAHs (active contracts with FiMVO): 392

The number of Product Master data: 8 900

The number of Batches: 24 481



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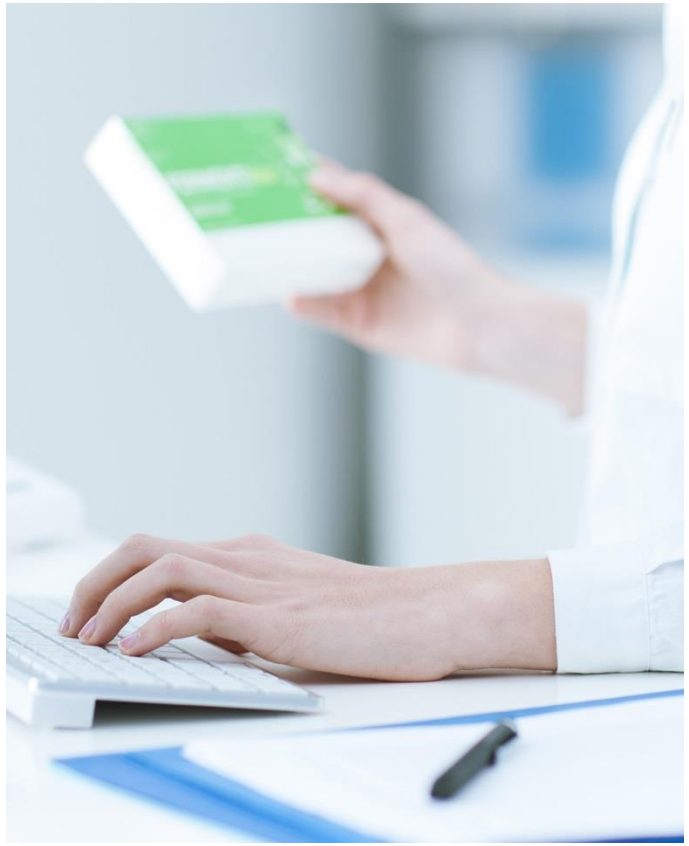
Alerts in general



Deviation classification in the FiMVS system

- L1: A deviation that the system repairs itself. This deviation does not appear to the user in any way.
- L2: The user receives notice of the deviation.
- L3: The System Administrator (EMVO or FiMVO) receives notice of the deviation.
- L4: More than one system administrator receives notice of deviation.
- L5: In addition to the user and system administrators, the OBP and the local competent authority are also notified of the deviation. This may be a falsified pack. L5 level deviations are referred to as alerts.

In principle:

- Deviations are divided into two groups: L1-4 and L5
- For the time being, L5 alerts are not automatically forwarded to Fimea

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When does the FiMVS system alert?

Cases where the alert may result from a potential falsification:

Product Code	Batch	Expiry	Serial number	Case
Unknown	N/A	N/A	N/A	Product code is not found in the entire EMVS[1]
Active	**Not found**	N/A	N/A	Batch is not found in the entire EMVS [1]
Active	Active	**Different**	N/A	Expiry in query differs from NMVS data
Active	**Different**	Correct	Active	Batch data does not match serial number[2]
Active	Active	Correct	**Inactive**	Inactive serial number
Active	Active	Correct	**Unknown**	Serial number is not found in the entire EMVS

[1] If the product code or batch data is not found in the FiMVS system → IMT query via the EU Hub to another national system
[2] Batch data error, does not need to be an actual batch number

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Alert types

- Unknown product code
  - A majority of these alerts are caused by non-EU-serialized packs (”Indian packs” with incorrect GTIN in the 2D data matrix)
  - Some alerts also caused by 1) OTC products, 2) medical devices, 3) non-EU-serialized packs imported from outside the EU for compassionate use, all bearing a 2D data matrix on the pack
- Failed to find a batch
  - Also some of these alerts are caused non-EU-serialized packs (”Indian packs” with correct NTIN/GTIN in the 2D data matrix)
  - Occasional failures by OBPs to upload Product Pack Data to FiMVS (will be detected by the wholesaler)
- Expiry date mismatch
  - No longer an issue, OBP data entry errors are detected by the wholesaler
  - Mismatch between 2D data matrix and FiMVS, in some cases shelf life has been incorrectly printed on packs
  - May also be caused by incorrect manual data entry by the end user

Alert types

- Batch ID does not match serial number in FiMVS
  - Practically all caused by end user data entry errors
- Unknown serial number
  - Usually end user data entry errors
  - In some cases a part of the batch data has not been uploaded in FiMVS
- Pack is already inactive
  - Caused by the end user performing a Dispense transaction for the same pack many times
  - FiMVS allows the same end user to perfom the Dispense transaction by scanning the 2D data matrix four consecutive times before raising an alert (double dispense functionality)
  - If, however, the pack is first dispensed by scanning and then by manual transaction (or vice versa), FiMVS alerts immediately after the second Dispense transaction
  - Also, for IMTs an alert is raised immediately after second decommisioning by the same end user

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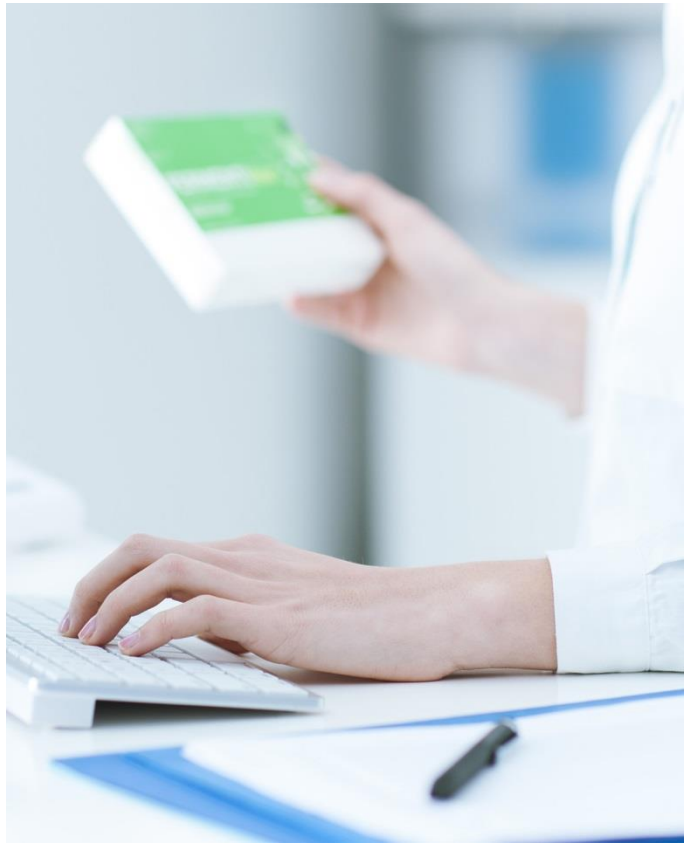
Statistics on alerts in FiMVS



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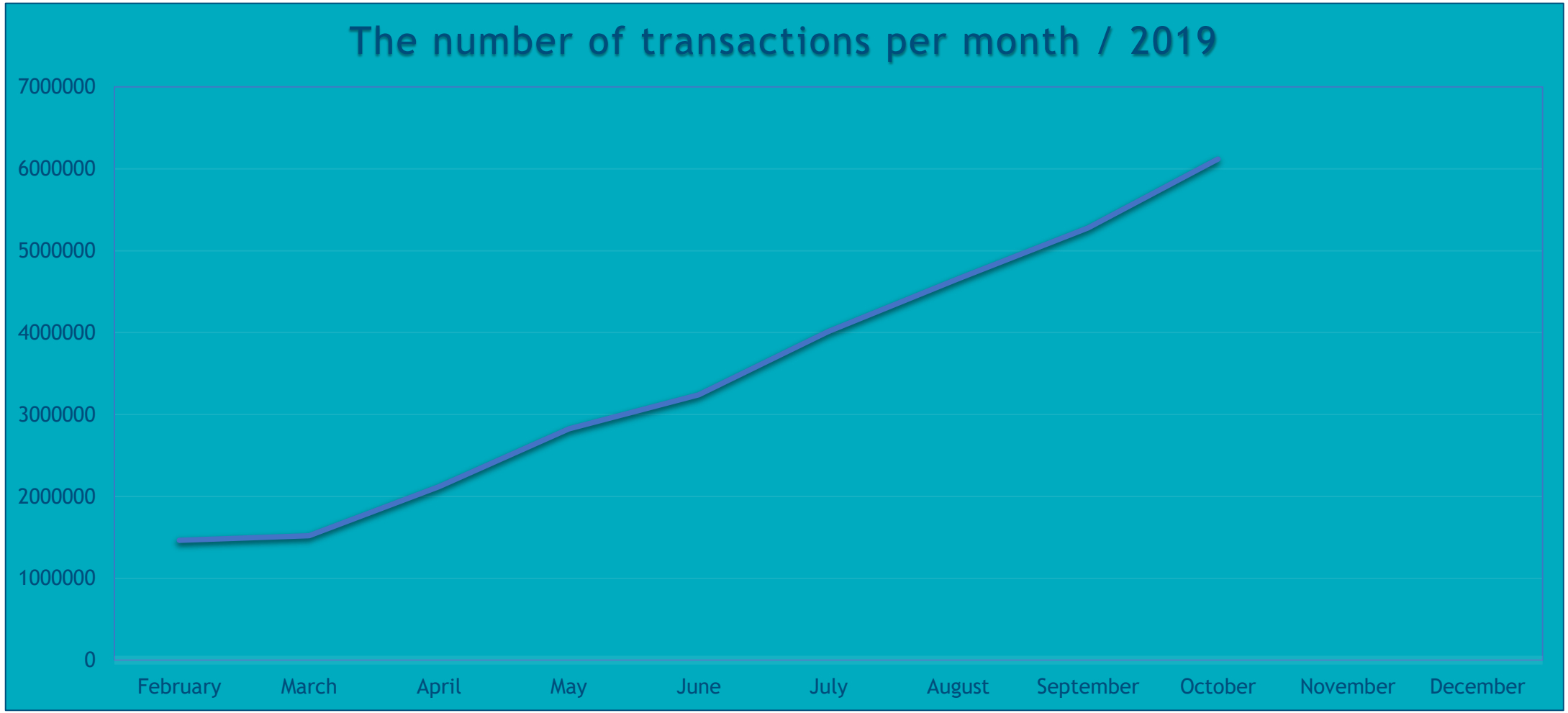
The number of transactions per month / 2019



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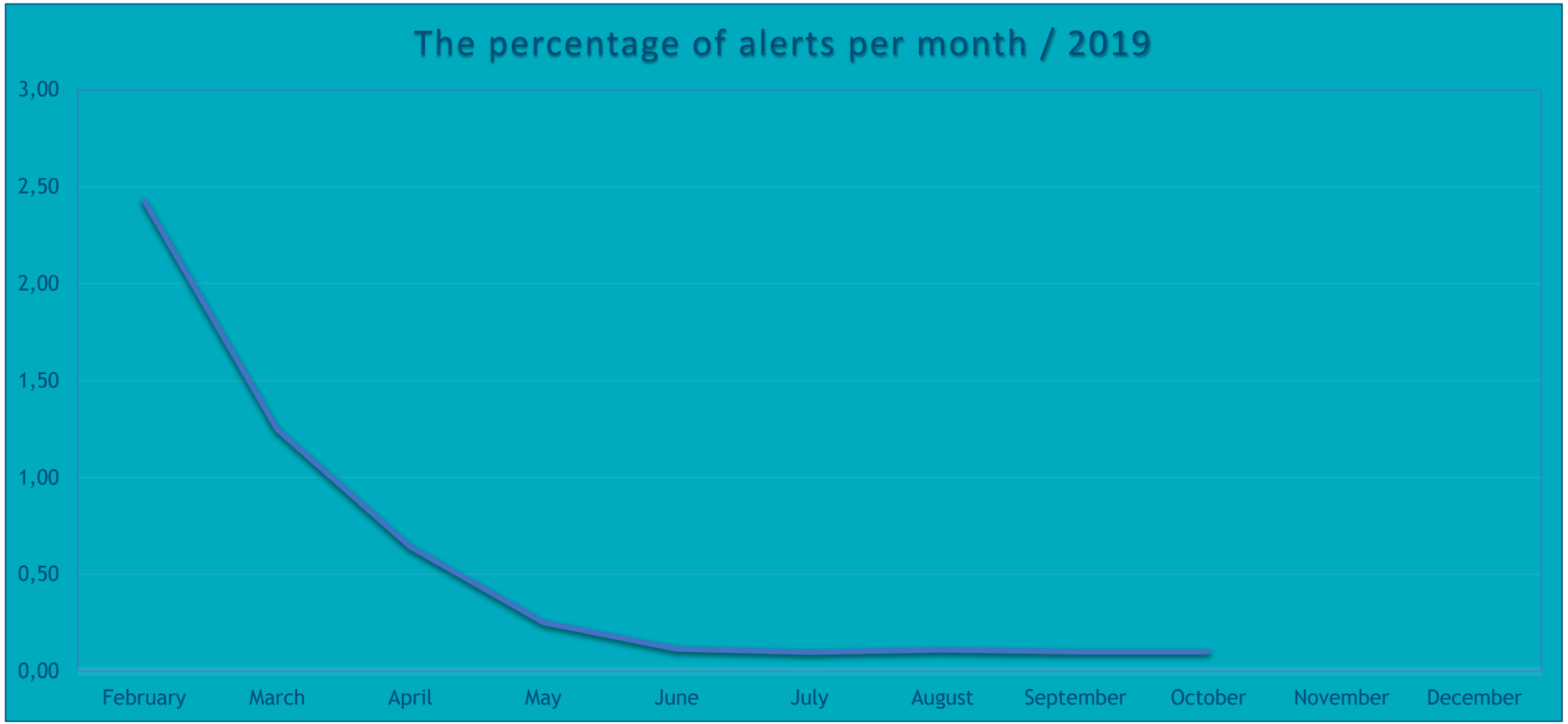
The percentage of alerts per month / 2019



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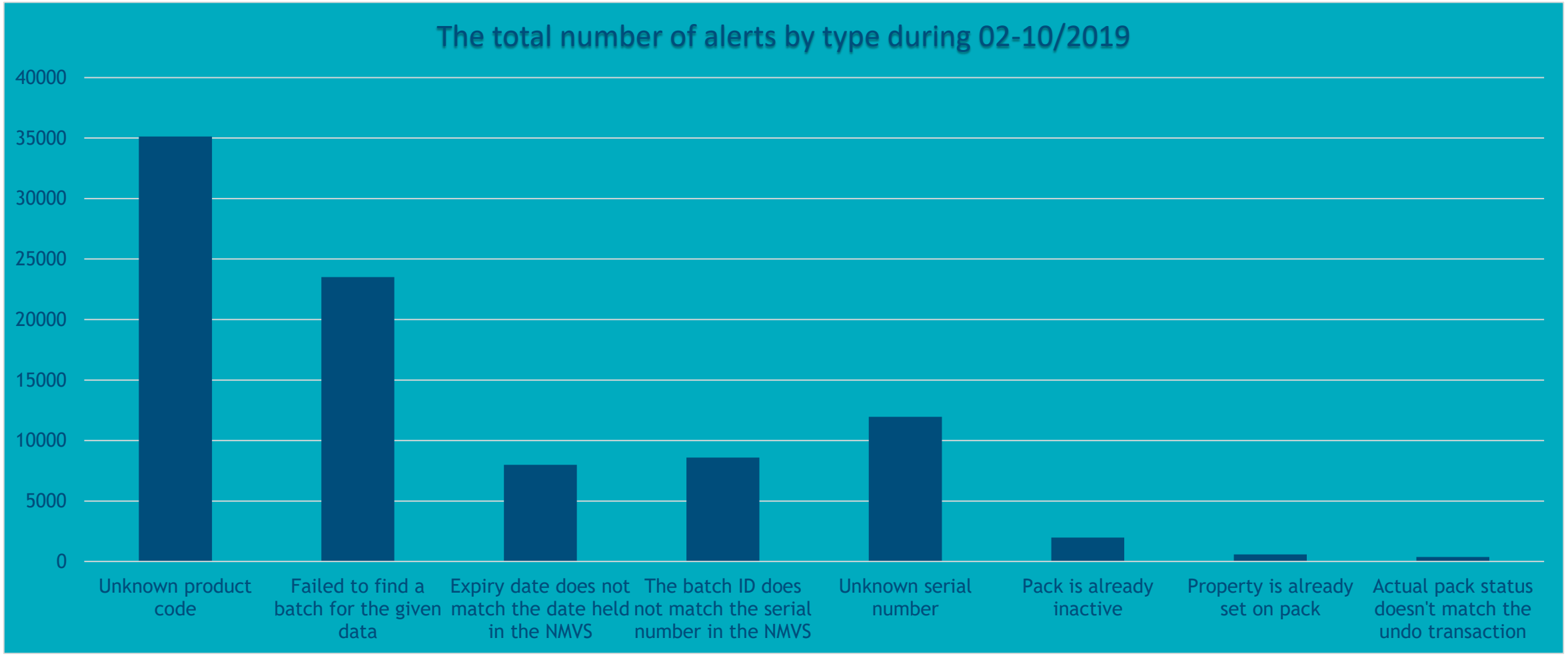
The total number of alerts by type during 02-10/2019



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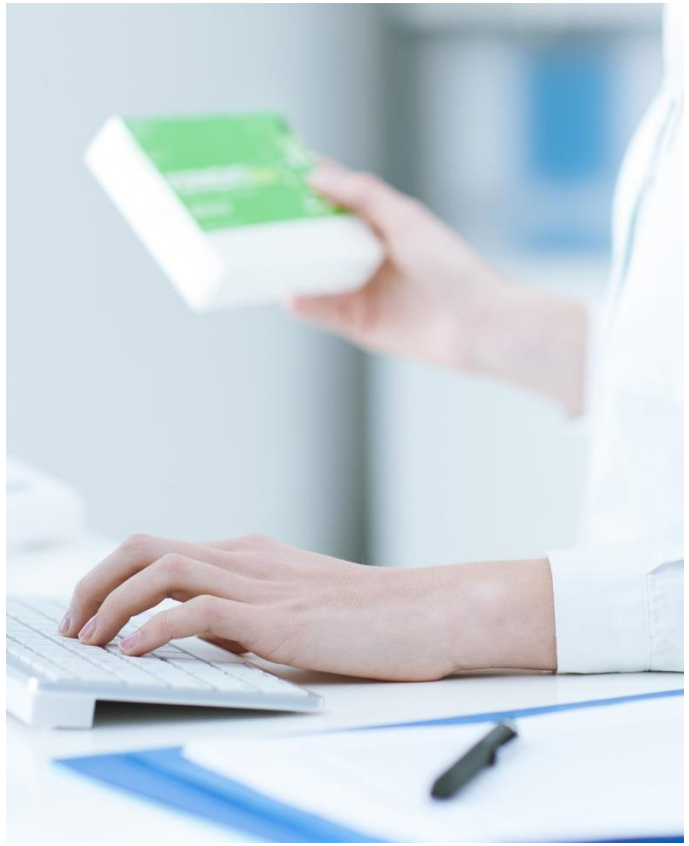
Approaching the end of the soft launch period



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End of the soft launch

- In practice, the soft launch means that pharmacies, hospital pharmacies, and dispensaries do not need to respond to an alert from the medicines verification system if:
  - The batch has been released before February 9th 2019, AND
  - The cause of the alert is 1) unknown product code OR 2) missing batch information OR 3) expiry date mismatch
- However, with some exceptions, wholesalers must solve all alerts before these packs and batches can be moved to the warehouse.
- In this context, it is particularly important for pharmaceutical companies to note that batches released after February 9th 2019 are not covered by the soft launch. All batches released after this date must include the safety features required by the Delegated Regulation 2016/161 and must be uploaded to the medicines verification system before release for distribution. Likewise, any alerts caused must be resolved.

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End of the soft launch

- Actors in the pharmaceutical distribution chain have jointly decided to continue the soft launch of the medicines verification system until January 31st 2020.
- The number of alerts has already fallen to a low level (on average, one alert per 1000 verified packages). End users have gained experience with the operation of the system and the resolution of various alerts and error situations. Over the next months, IT systems will be further developed.
- In addition, the FiMVS system will receive new features with the next system upgrade, which will further reduce the number of alerts which are currently covered by the soft launch.
- After January 31st 2020, all alerts in the medicines verification system must be resolved before the alerting pack can be dispensed to the patient. This requires that the end user's IT system clearly notifies if the pack alerts.

EMVO Newsletters

- Latest newsletters from EMVO (https://emvo-medicines.eu/news-events/)
  - 15.10.2019: EMVO would like to remind OBPs that for Multi-Market Packs (MMPs), the master, batch and pack data must be loaded to all the markets within the defined cluster, i.e. for all markets to which the MMP can be distributed.
  - 17.10.2019: When recalling a batch, the OBP needs to refer to the Product Code, the Batch ID, the reason for recall and state the list of affected markets. The EU Hub will then inform the affected markets of the batch recall requirement. It is vital that batch recalling should only be performed only **once** and not multiple times on the same batch.
- Subscribe the newsletters here: https://emvo-medicines.eu/news-events/newsletter/

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Challenges & way forward

- Data management by OBPs
- Non-EU-serialized packs => whitelist feature in the upcoming software release => FiMVS will inform the end user if the product code is on the whitelist
- Open sharing of information and experiences among the stakeholders
- Fine-tuning of barcode scanners
- Development of end user IT systems so that the user can easily see the information content of the request that was sent to FiMVS and the reply from FiMVS and can distinguish between a deviation and an alert
- The entire supply chain should have enough information about the reasons for different alerts and of their solutions => FiMVO will provide a guide / instructions for all by the end of this year

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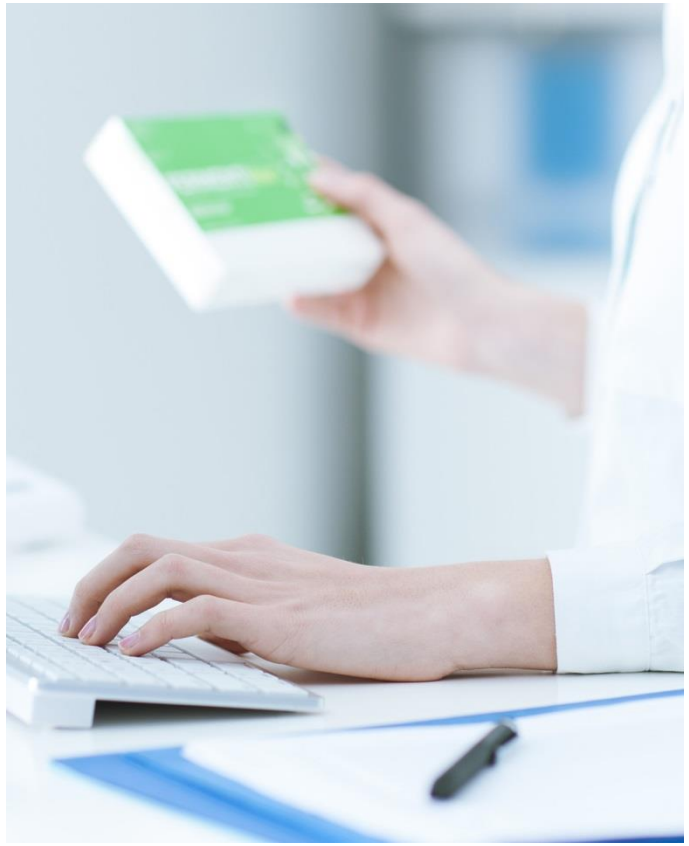
Thank You!

https://www.laakevarmennus.fi/en/news



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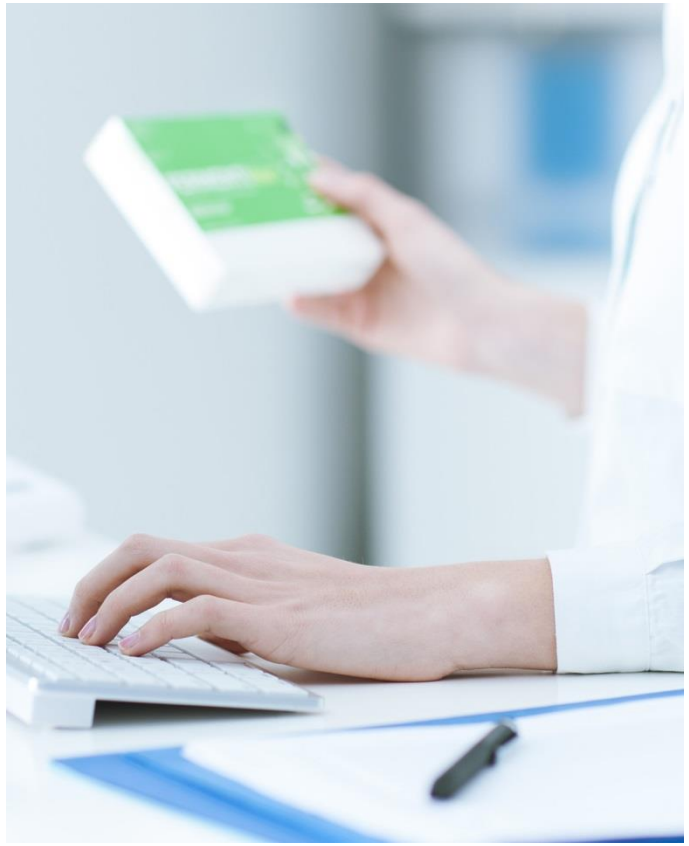
Q & A

Any questions and/or comments?



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Contact us!

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