MAH Training 27.10.2022 – Agenda

- Introduction
  - Maija Gohlke, General Manager
- Contract and Invoice matters
  - Henna Rönkkö, Assistant
- Guest speaker: The ABC of medicines verification for MAHs
  - Paul Mills, Melior Solutions

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Introduction

Why is the medicines verification system necessary?

We aim to **prevent falsified medicines from entering** the legal supply chain.

We improve patient safety. Patients can be sure that they get **genuine medicines** when they buy them from legal pharmacies and online pharmacies.

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Legislation

Falsified Medicines Directive 2011/62/EU

Variety of measures to prevent falsifications

Delegated Regulation (EU) 2016/161

Applies as such in all Member States

Commission Q&A document gives more insight (but isn't legally binding)

National legislation and guidance

No separate guideline by Fimea

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This is how we safeguard the legal supply chain from falsified medicines

Prescription medicine packs have safety features on them

- Unique identifier (2D code)
  - Product code
  - Unique serial number
  - Batch number
  - Expiry date
- Anti-tampering device (ATD)

Unique identifiers are uploaded to a European wide database and used from national systems.

Anti-tampering device

- To be decided by pharma companies
- CEN standard prEN 16679 Tamper verification features for medicinal product packaging
- At the point of dispense it must be checked that the mechanism is intact

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Governance of the system

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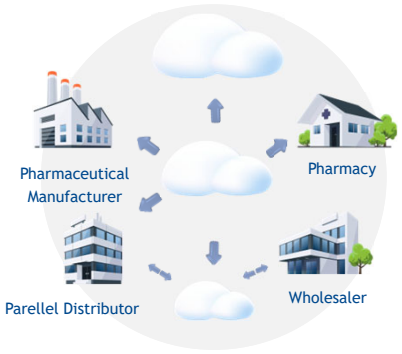
Who pays?

Repository system (EU Hub & national systems)



Pharmaceutical Industry

Installations for pack coding

Pharmaceutical Industry

Cost of connecting to the system and equipment purchases

Pharmacies and wholesalers

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Northern Ireland
Austria
Belgium
Switzerland
Bulgaria
Sweden
Croatia
Spain
Cyprus
Slovenia
Czech Republic
Slovakia
Denmark
Romania
Estonia
Portugal
Finland
Poland
France
Norway
Germany
Netherlands
Greece
Malta
Hungary
Luxembourg
Iceland
Lithuania
Ireland
Liechtenstein
Latvia
Italy
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FiMVO Board

Pharma Industry Finland
Nina Ekholm-Wenberg, Janssen-Cilag

Finnish Generic Pharmaceutical Association
Heikki Bothas

Orion Pharma
Juho Hellman

The Association of Pharmaceutical Distributors
Kai Kaasalainen, Tamro

The Association of Finnish Pharmacies
Charlotta Sandler

Suppliers of Parallel Imported Medicines of Finland
Tia Geijer

FiMVO Office

General Manager
Maija Gohlke

QA Manager
Teijo Yrjönen

Service Manager
Mirka Koski

Finance and administration Manager
Taina Tummavuori

Assistant
Henna Rönkkö

Alert Management & End User Management
Stanley Eklund

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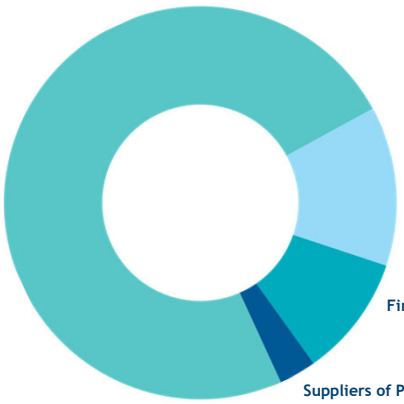
Non profit limited company

Shareholders



Pharma Industry Finland 74 %

Orion Oyj 13 %

Finnish Generic Pharmaceutical Association 10 %

Suppliers of Parallel Imported Medicines of Finland 3 %

0,01 % The Association of Finnish Pharmacies

0,01 % The Association of Pharmaceutical Distributors

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100%
Users

0,04%
Alerts

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Contract and Invoice matters

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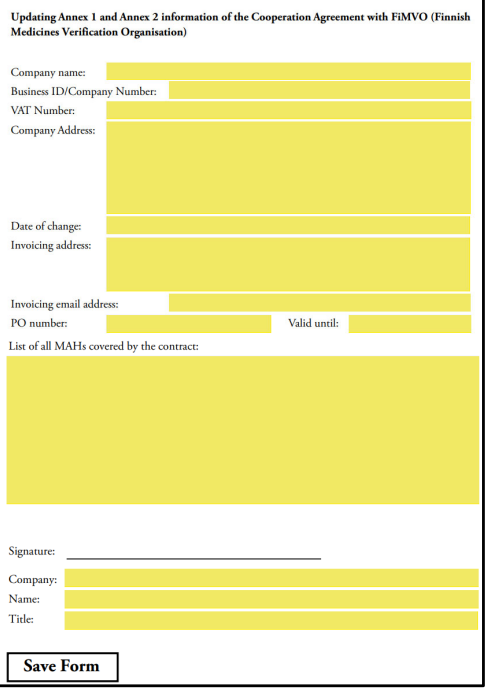
When do you need to update the contract?

- Deletion or addition of a MAH
- Merging of MAHs
- Invoicing information
- Company information
- PO number

-> Use the Annex I and II form

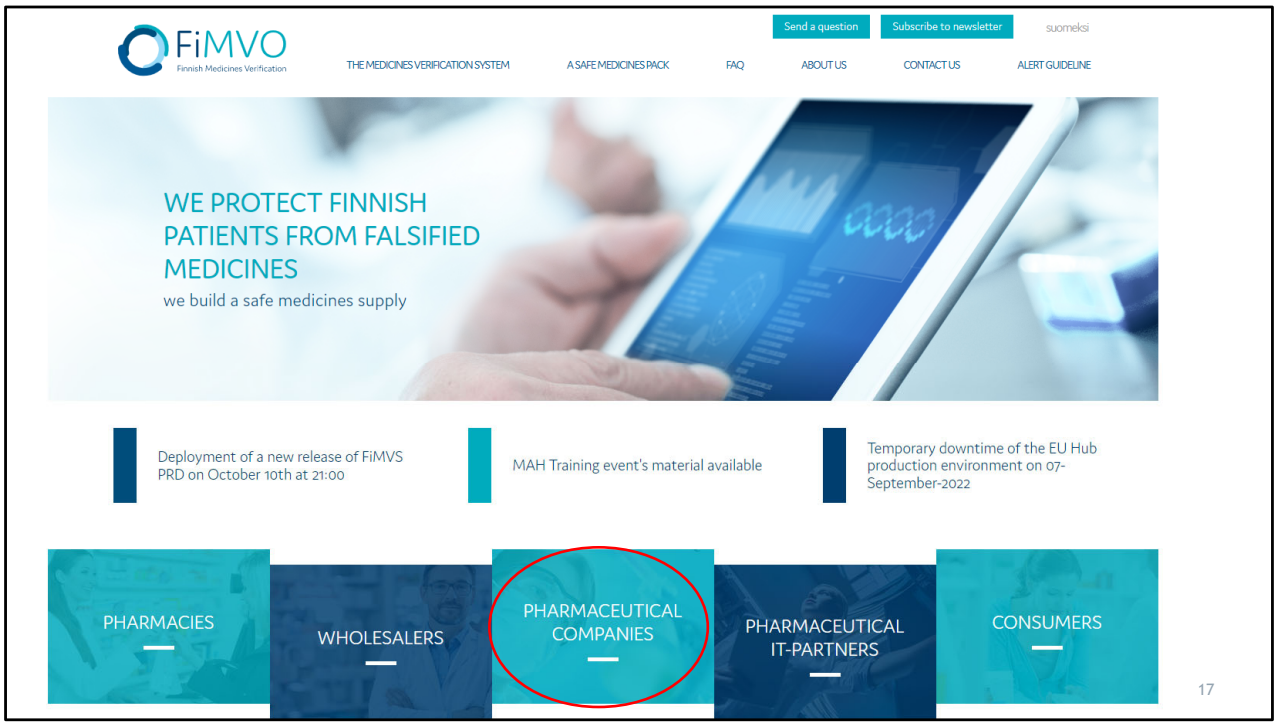
-> info@fimvo.fi



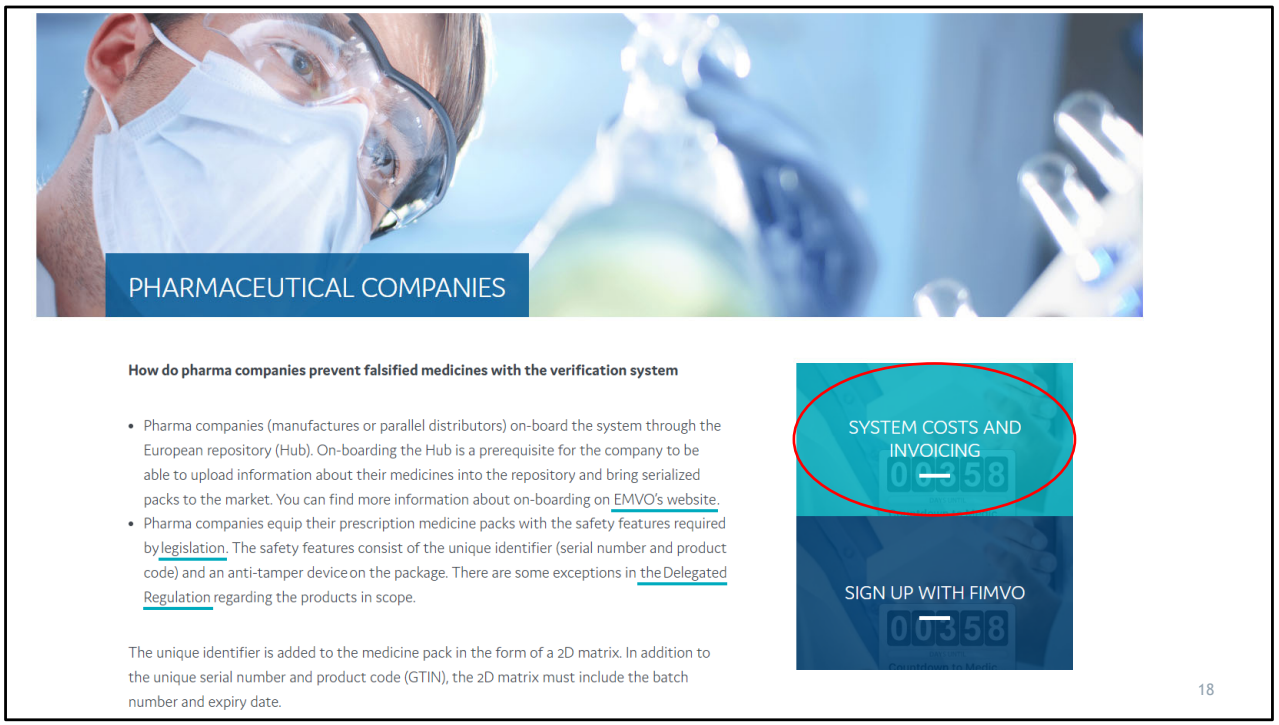
Updating Annex 1 and Annex 2 information of the Cooperation Agreement with FiMVO (Finnish Medicines Verification Organisation)

Company name:
Business ID/Company Number:
VAT Number:
Company Address:
Date of change:
Invoicing address:
Invoicing email address:
PO number:
Valid until:
List of all MAHs covered by the contract:
Signature:
Company:
Name:
Title:
Save Form

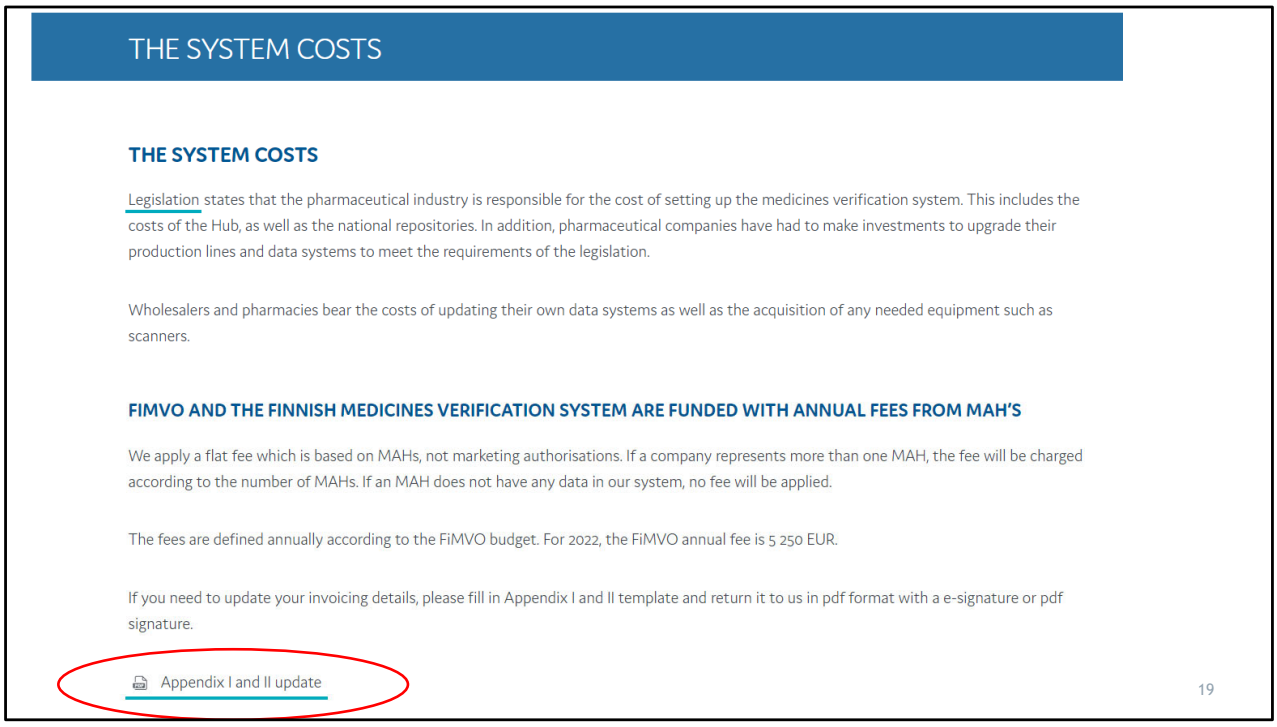
Always fill in the whole form and send us a signed document
Write the MAH name not the product name on the List of all MAHs covered by the contract.
If there is only one MAH represented in the contract with the same name as company name, please write the MAH/company name.



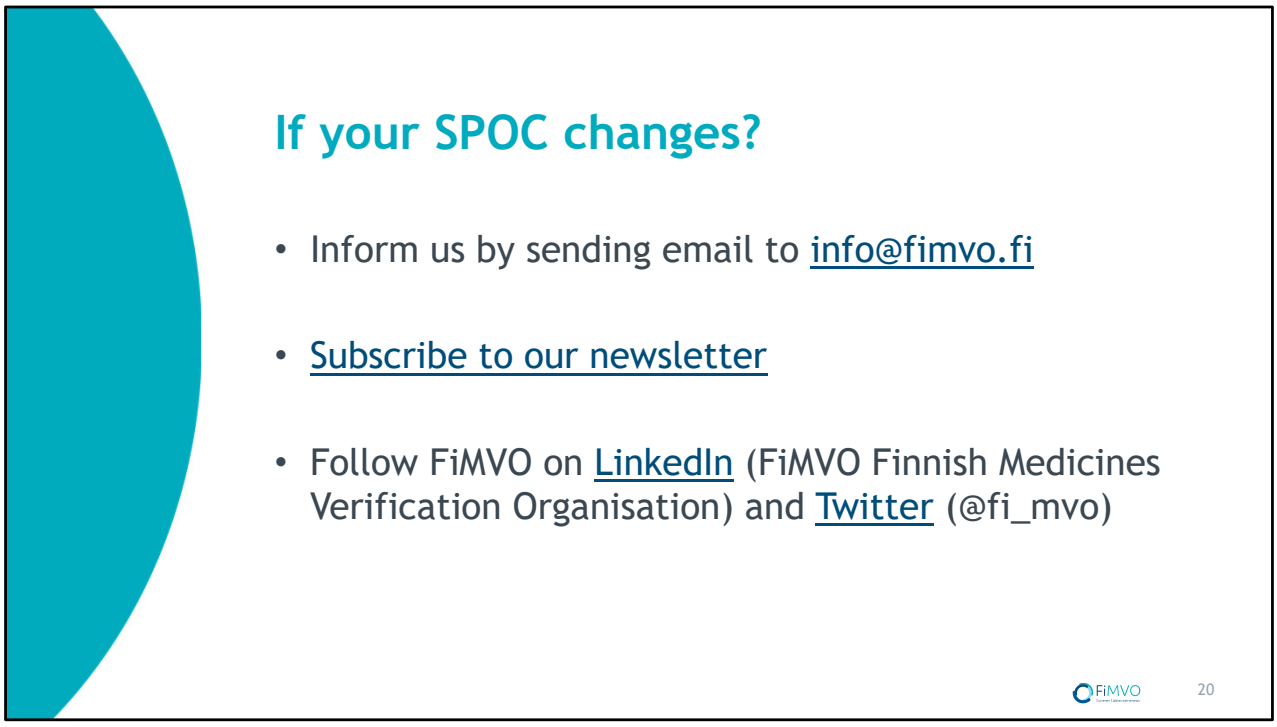
https://www.laakevarmennus.fi/en
You can find the Annex I and II form by clicking Pharmaceutical Companies on the front page



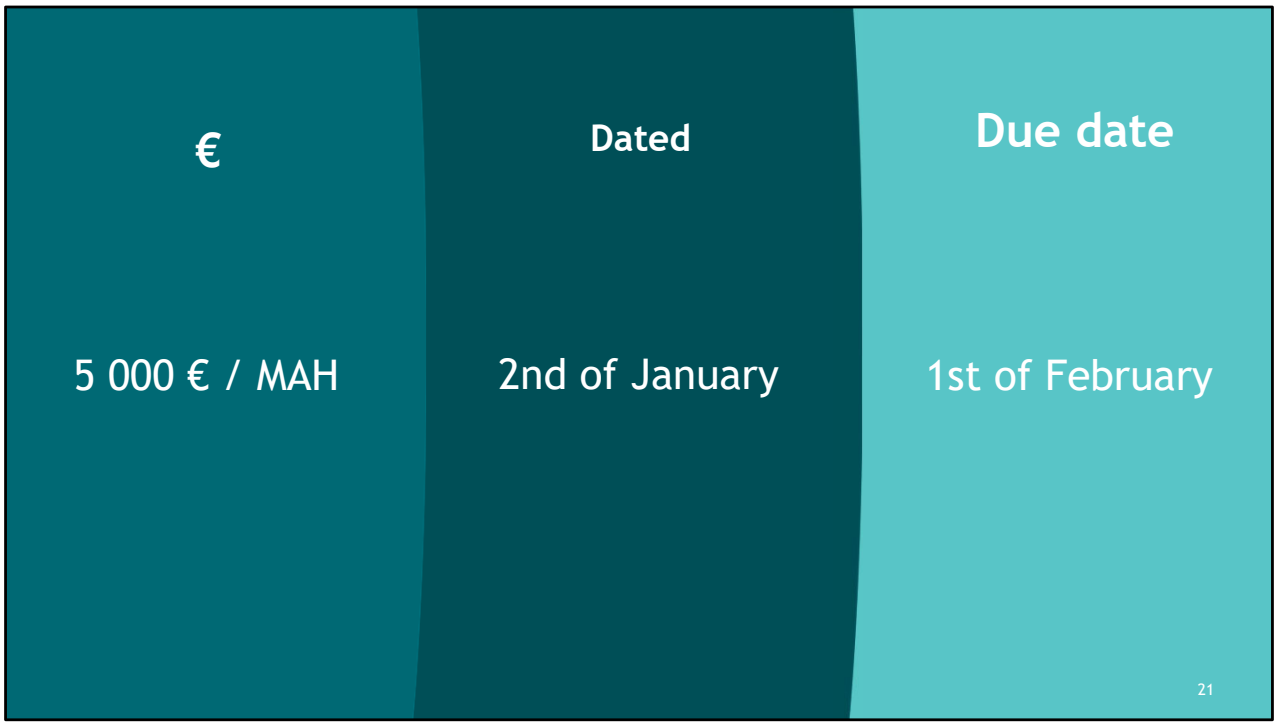
https://www.laakevarmennus.fi/en/pharmaceutical-companies
Then clicking on System costs and invoicing (annex is also found on Sign up with FiMVO)



And here you can find the form
https://www.laakevarmennus.fi/en/system-costs



Everybody can subscribe the newsletter! It is send around 4 times a year.
We are also active on LinkedIn and Twitter and we share lot of information through these platforms.



FiMVO applies an annual fee based on the number of MAHs on the contract, there is no registration fee.
The annual fee for 2023 will be 5000€ per MAH, the invoices will be dated to 2nd of January and the due date will be 1st of February 2023 (our payment term is 30 day net)
We inform next year's MAH fee on September.

If you need a PO number

- Please fill in whole the Annex I and II form
- Sign it
- Send it back to us (info@fimvo.fi)

- **Let us know asap**

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If you need a PO number to be mentioned on the invoice, please fill in the Annex I and II form and send it back to us signed.

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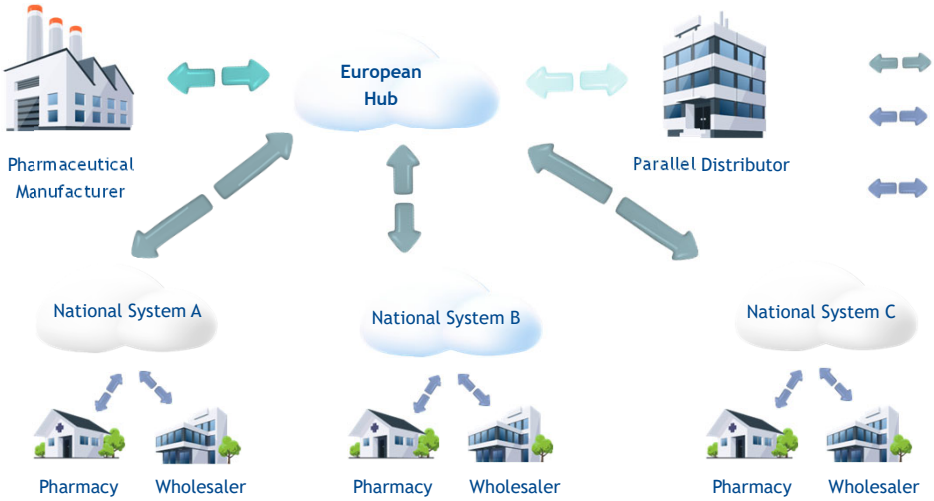
How does the system work?

How does the EMVS Work?

- Please ask questions as you think of them, and I'll try to keep on time.

- The EMVS is a really simple data distribution system.
- It uses a distributed infrastructure model.
- OBPs load data to one single component we call the "Hub".
- The Hub then sends the data to the markets where the packs are meant to be sold.
- Pharmacies, Wholesalers and Hospitals etc. can then scan packs and have the data checked against the local NMVS

European Medicines Verification System



- Manufacturer: data upload + voluntary verification
- Parallel Distributor: mandatory verification + data upload
- Periodic cross-region update
- Pharmacy: mandatory verification
- Wholesaler: voluntary verification

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Multi-Market Presentations

- This is where the product is produced for multiple markets using the same packaging.
- The data for these packs is loaded to all of the sales markets
- When a pack is decommissioned in one market, because the system knows this is a multi-market presentation, a synchronisation process starts.
- The market where the pack was decommissioned, sends a message to the Hub telling the hub that a specific pack (serial number) has been decommissioned.
- The hub uses the product code and batch code information to work out in which markets the pack data is loaded.
- The hub then sends a message to each of the other markets, informing them that the pack has been decommissioned.

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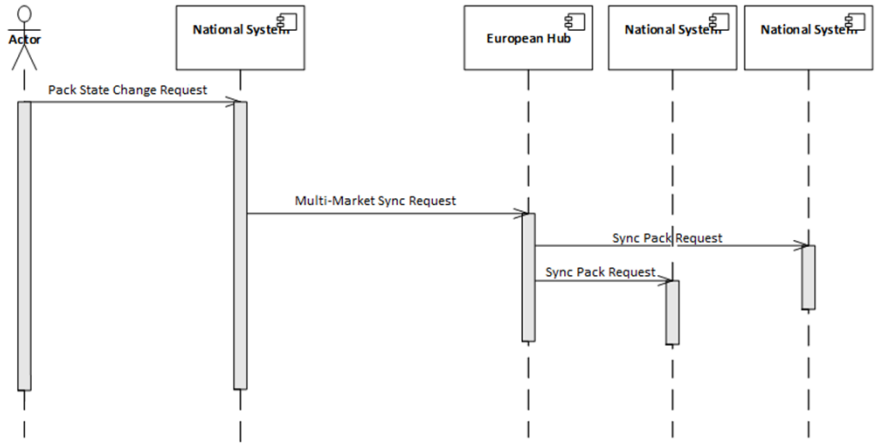
Multi-Market Presentations



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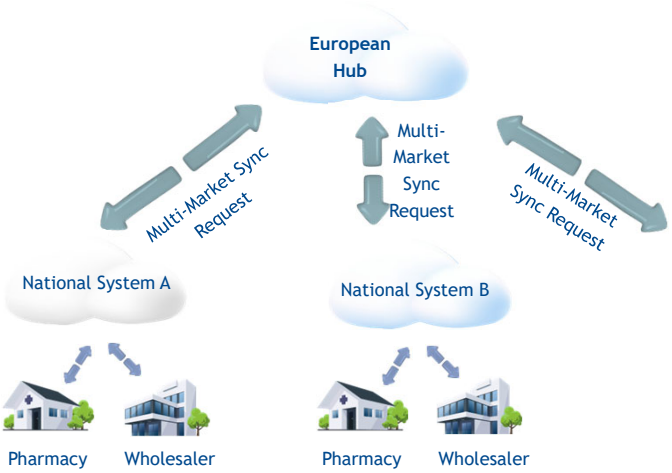
Multi-Market Presentations



- Manufacturer: data upload + voluntary verification
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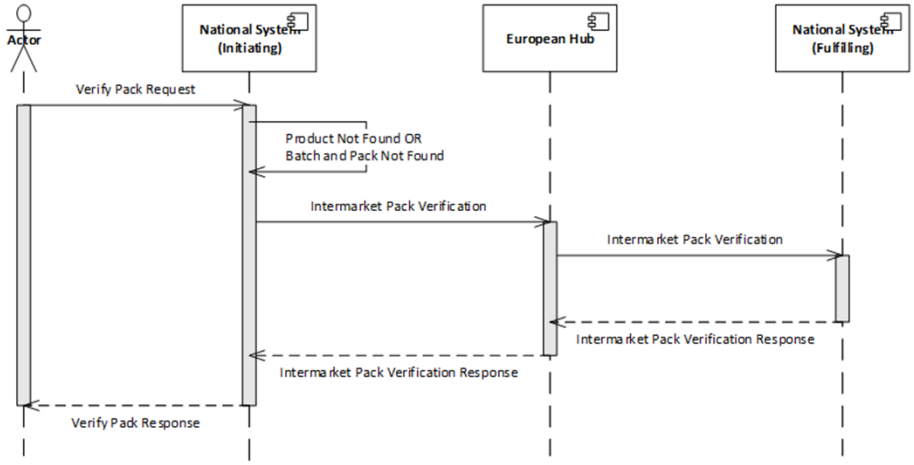
Inter-Market Transactions

- This is where the product pack being scanned is a valid pack but the data is not available in the local market NMVS.
- It was originally scoped to handle Article 5 (e.g. compassionate use) products.
- Here the pack is scanned locally
  - The local NMVS cannot locate the product and batch
  - Before raising an alert, the local NMVS asks the Hub if it knows anything about the batch
  - If the Hub does then the Hub asks the NMVS where it knows the data resides and receives a response, which it then returns to the sending NMVS.

Inter-Market Transactions



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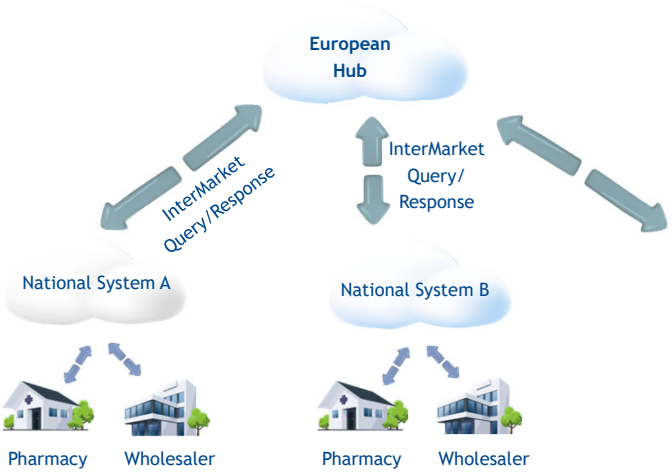
Inter-Market Transactions



- Manufacturer: data upload + voluntary verification
- Parallel Distributor: mandatory verification + data upload
- Periodic cross-region update
- Pharmacy: mandatory verification
- Wholesaler: voluntary verification

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Alerts

- What is an Alert?
  - It's essentially the signal that something simply isn't quite as it should be.
- The pack might be unknown to the system – it is therefore a potential counterfeit.
- The data on the pack might not match the data stored.
- The pack may have already been decommissioned – therefore it might be a duplicate.
- The scanning equipment might be incorrectly configured and reading the data incorrectly

- There are lots of reasons for alerts and many of them are self-inflicted ;-)

Alerts – OBP Errors

- Date information.
  - Pack Datamatrix code contains the GS1 compliant (currently) YYMM00 format, i.e. the day value is the end of the month. However the data sent to the EMVS was in the form YYMMDD where DD was actually set to the value of the last day of the month. YYMM00 does not equal YYMMDD
- Market Information
  - As an OBP, you specify which markets you actually commercialise the produce - but you forget one or more, or maybe worse, you specify too many.
  - Specifying too many won't result in an Alert but will end up with you being asked to pay more NMVO fees if you load data to markets where you do not actively commercialise the product.
  - Do not enter all EU markets for a centrally authorised product unless you actively sell the product in all markets.
- Batch Data (and other fields).
  - You use mixed case data e.g. Batch01. Do not use mixed case, always use upper case where possible, lower case is not preferred (as it can cause issues at the point of scanning)
  - Odd characters e.g. ( ) /\ * £ Try where possible to limit the use of non-numeric and non-alphabetic characters please - again, potential scanning issues can be caused.

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Alerts - OBP Errors

- Batch Data
  - You forget (?!) to upload the data for a batch that has been shipped. This is guaranteed to produce many alerts, at least one per pack produced.
  - You upload the data for a batch more than once. You will receive many errors for this (#A32)
- Decommissioning
  - OBP decommissions pack data more than once. Each pack with a duplicate decommission will result in one Alert for you to process.

- Remember, for each Alert you process, the NMVO also must process it and potentially the NCA will see it. Just take care and don't invoke processes that result in Alerts being produced unnecessarily.

Alerts – End User Errors

- Batch and Serial Number Data – case sensitivity
  - You use mixed case and/or special characters.
  - The scanning equipment in the supply chain is simple and not set up correctly. Someone locally presses the "Caps Lock" key on the terminal keyboard and suddenly the data read e.g. = Batch01 comes out as batch01 or BATCH01. The transaction will then fail and an alert will be raised.
  - Yes it's an end user configuration issue.
  - Yes they should sort themselves out but
  - You can avoid the issue by not mixing the case.
- Batch and Serial Number Data – special characters and keyboard mapping
  - As with the above, this is totally a scanner set up issue but, you can help avoid unnecessary alerts by being sensitive to the issues.
  - Some localisations of keyboard struggle with characters like Z or Y or (or) etc. You cannot avoid characters like - and / and \ so easily but where you can, try and avoid their use whilst we help to educate the end user community about the issues they cause.

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Advice

- If in doubt – ask.
  - EMVO can often help (helpdesk@emvo-medicines.eu)
  - FiMVO may also be able to help
  - EMVO is your first point of contact for help as an OBP
- Check out the EMVO website for the documentation that's available – there's a large knowledge base on the website
- If you do mess up, and we all do at some stage, please check with either EMVO or FiMVO before you try and fix it yourself (unless you've done it before and know what to do!)

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EMVS Master Data Guide is helpful too: https://emvo-medicines.eu/new/wp-content/uploads/EMVS-Master-Data-Guide_updated.pdf
EMVO's website: https://emvo-medicines.eu/
EMVO's knowledge base: https://emvo-medicines.eu/knowledge-database/

Follow the news and contact us!

- Social media: FiMVO.fi I LinkedIn I Twitter
- Subscribe to FiMVO's newsletter: https://uutiskirje.fimvo.fi/
- For alerts, system and data related inquiries and support, please use: nmvs@fimvo.fi
- For contracts and invoicing, please use: info@fimvo.fi

MAH Training event's 20.9.2022 material available

- The MAH Training 20.9. included topics:
  - Contract and Invoice matters - next year's fee and timetable
  - Guest speaker: Medicines verification from a hospital pharmacy perspective – Tiina Miettinen, Pharmacist from HUS Apteekki (the Hospital District of Helsinki and Uusimaa)
  - Alert Status and Alert Management in Finland
  - Tips for MAHs
- You can find the material on our web site: https://www.laakevarmennus.fi/en/news/mah-training-events-material-available

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Thank You!