Information Event Pharmaceutical Companies

amvs
Austrian Medicines Verification System

Livestream Event

25.06.2024

Agenda

Austrian Medicines Verification System

- AMVS Organisation, Status Agreements and Fee Model
- Coding and Data Quality
- Current topics at EU Level
- Alert Statistics and Sources of Error
- Guidance Alert Management and Status Start Phase Operations
- Alert Management – EAMS and ADAM
- 5 Years of Medicines Verification in Slovakia

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AMVS Organisation

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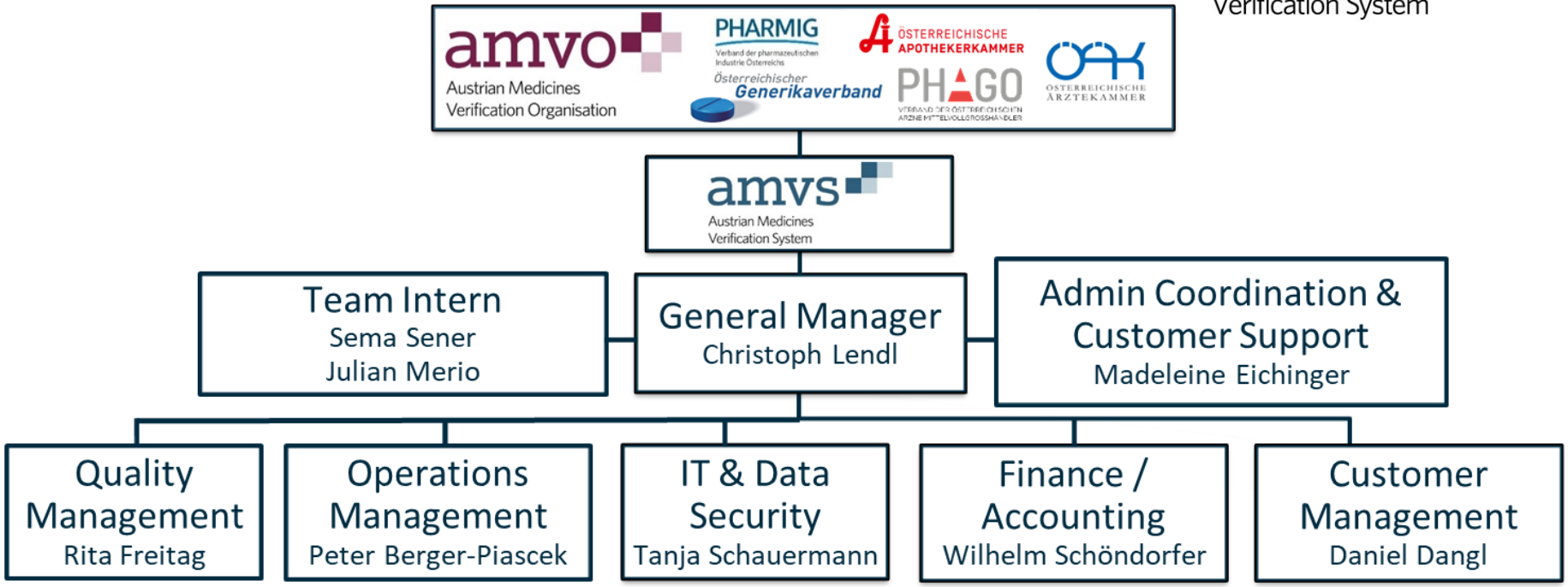
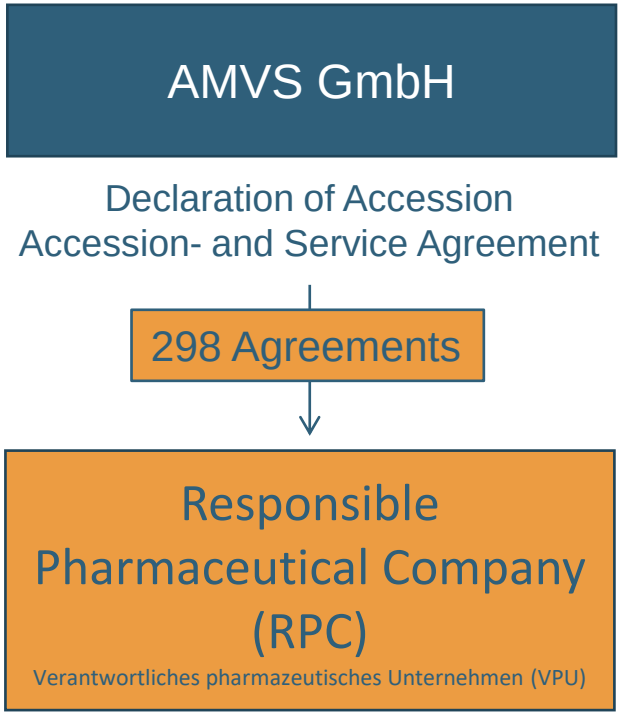


Conctractual Relations – Responsible Pharmaceutical Companies

Austrian Medicines Verification System



Status: 17.06.2024

Operational Fees
Fee Model since 2024

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Fixed Turnover based Part

Turnover € / User p.a.	Fee € / User p.a.
< 100k	360
100k-1.5 Mio	1 080
1.5-3 Mio	2 160
3-10 Mio	3 600
10-20 Mio	5 400
20-30 Mio	10 800
30-50 Mio	18 000
50-70 Mio	25 200
70-100 Mio	32 400
100-150 Mio	39 600
150-200 Mio	46 800
200-250 Mio	54 000
> 250 Mio	61 200

Operational Fees
Fee Model since 2024

Austrian Medicines Verification System

Variable Volume-based Part

Price-Quantity Scale p.a.	€/serial number
≤ 2.000.000	0,007
≥ 2.000.001	0,003

Number of uploaded serial numbers based on AMVSystem

Operational Fees
Fee Model since 2024

Austrian Medicines Verification System

Invoicing:
3 invoices / year

Fixed Turnover based Part:
Turnover Declaration until 31st January — Invoicing until 28th February

Variable Volume-based Part:
Uploads January - June — Invoicing until 31st July
Uploads July - December — Invoicing until 31st January

Payment Deadline 30 Days

Contractual Relations – Endusers

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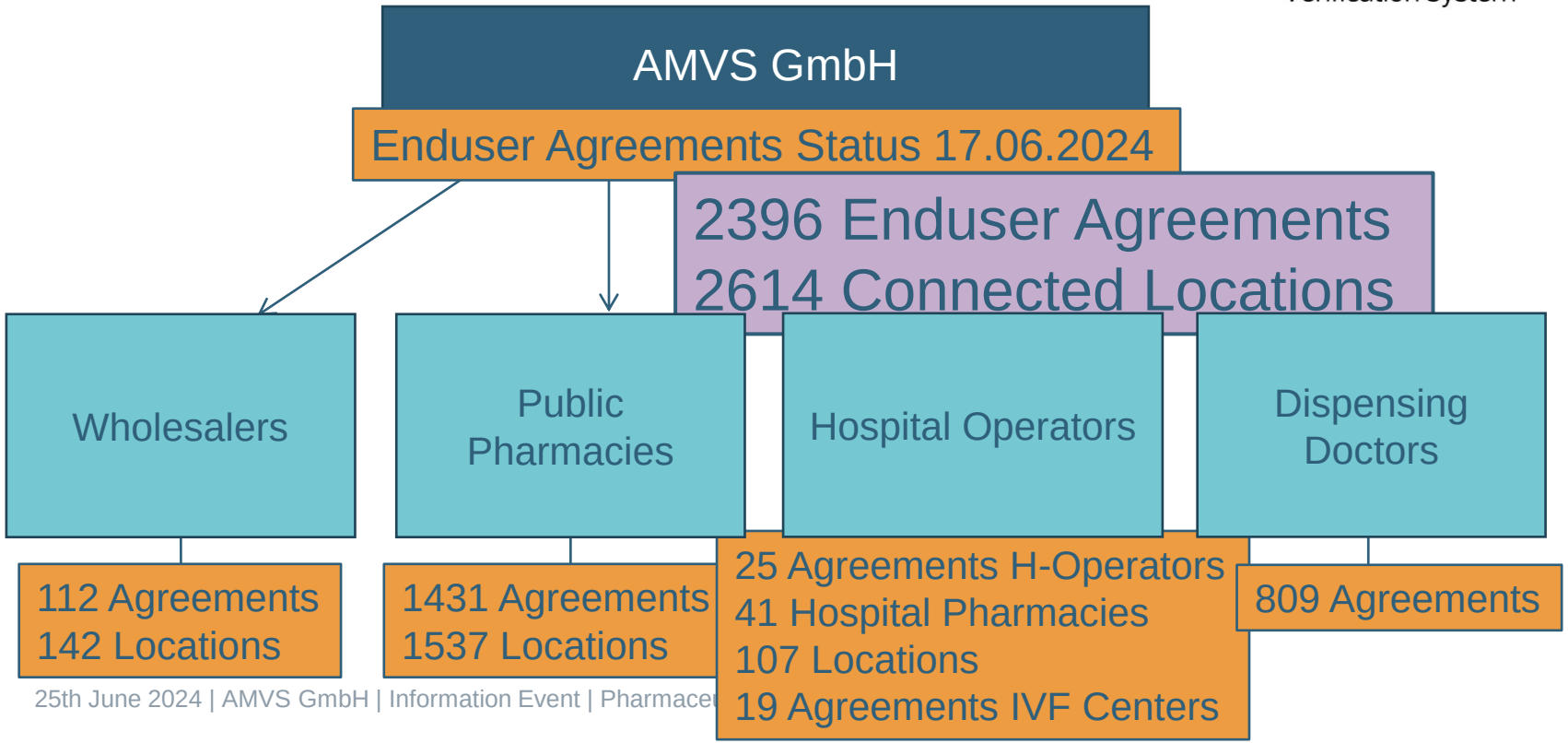

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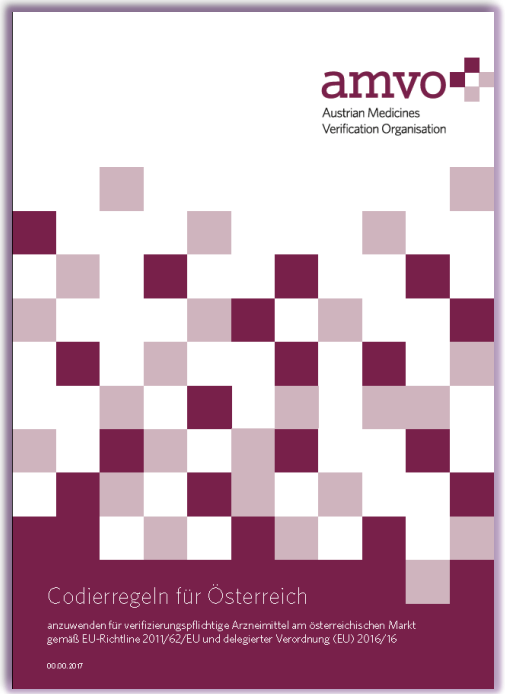
Coding and Data Quality



Coding Rules for Austria
Version 4.0 published in November 2020

German Version:
https://www.amvs-medicines.at/media/1693/amvo_codierregeln_v4.pdf
English Version:
https://www.amvs-medicines.at/media/1694/amvo_coding-rules_v4_en.pdf

Coding and Data Quality

Austrian Medicines Verification System

How does the pharmacy obtain further product information after scanning the DataMatrix code?

For **Single Market** AT Packs:
PC = NTIN AT, PZN included
→ No further action needed

For **Multi Market** Packs:
PC ≠ NTIN AT, no connection with PZN
→ PC **must be stored in Warenverzeichnis**!

Coding and Data Quality

Austrian Medicines Verification System

Do I still have to upload an NHRN for all products?

- Yes, the Austrian PZN (7 digits incl. its own check digit) must be uploaded for all products

- In June 2023, a check of the NHRN was implemented at the EU Hub. New master data for Austria can no longer be created without or with incorrectly generated NHRNs.

Coding and Data Quality

Austrian Medicines Verification System

Do I – for some reason – have to keep the 1D linear barcode?

- No, we recommend to
  - Not print any 1D linear barcode for new products
  - Remove the 1D linear barcode within the next package version

Coding and Data Quality

Austrian Medicines Verification System

New expiry date coding requirements will apply from January 2025

- Adaptation of GS1 specifications in March 2022
- "00" in the date field for the day should no longer be used
- To be implemented by 01.01.2025

EXAMPLE: 31st December 2025

currently allowed:	251200 and 251231
from 2025:	251231

Coding and Data Quality

EMVO Master Data: Upload of the Product Name

According EMVO Master Data Guide:
The (invented) name + strength + pharmaceutical form.

- For single market packs, use the national language
- For multi-market packs, use the name as it appears on the artwork or a concatenation of the name in each language suitable for the pack.

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Current topics at EU Level
Italy and Greece

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Delegated Regulation to be applied in both countries from 09.02.2025

Italy:

- NMVO founded
- General Manager Marcello Materrelli
- Arvato selected as blueprint provider

Greece:

- NMVO founded
- Blueprint provider decision not yet made

Current topics at EU Level
NIXIT

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NIXIT = Northern Ireland's withdrawal from the EMVS due to the Windsor Agreement of February 2023

Background: Since BREXIT, FMD was only applicable in Northern Ireland.

- From January 1 2025, UK/NI data can no longer be uploaded.
- The existing UK/NI data repository will be shut down (historical data will no longer be available) and the British NMVO SECURMED will be liquidated
- Single Market UK packs located in the Austrian market will generate a Level 1-4 notification
- There will be no change in behavior for Multi Market packs with UK in the Austrian market.
- EU packs that are delivered to the UK must be removed from the data repository with the status "Export".

Current topics at EU Level
NON FMD List

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Background: The NON FMD list is intended to prevent serialized packs that are not affected by the FMD from generating the message "unknown product code" at the end user.

Piloting of use is taking place in Belgium, Spain, Austria and Ireland

Piloting of use is limited to the following use cases:

- Medical devices, food supplements, imports from NON EU
- UK packs (batches) that were placed on the market before December 31 2024, but were not loaded into the data repository

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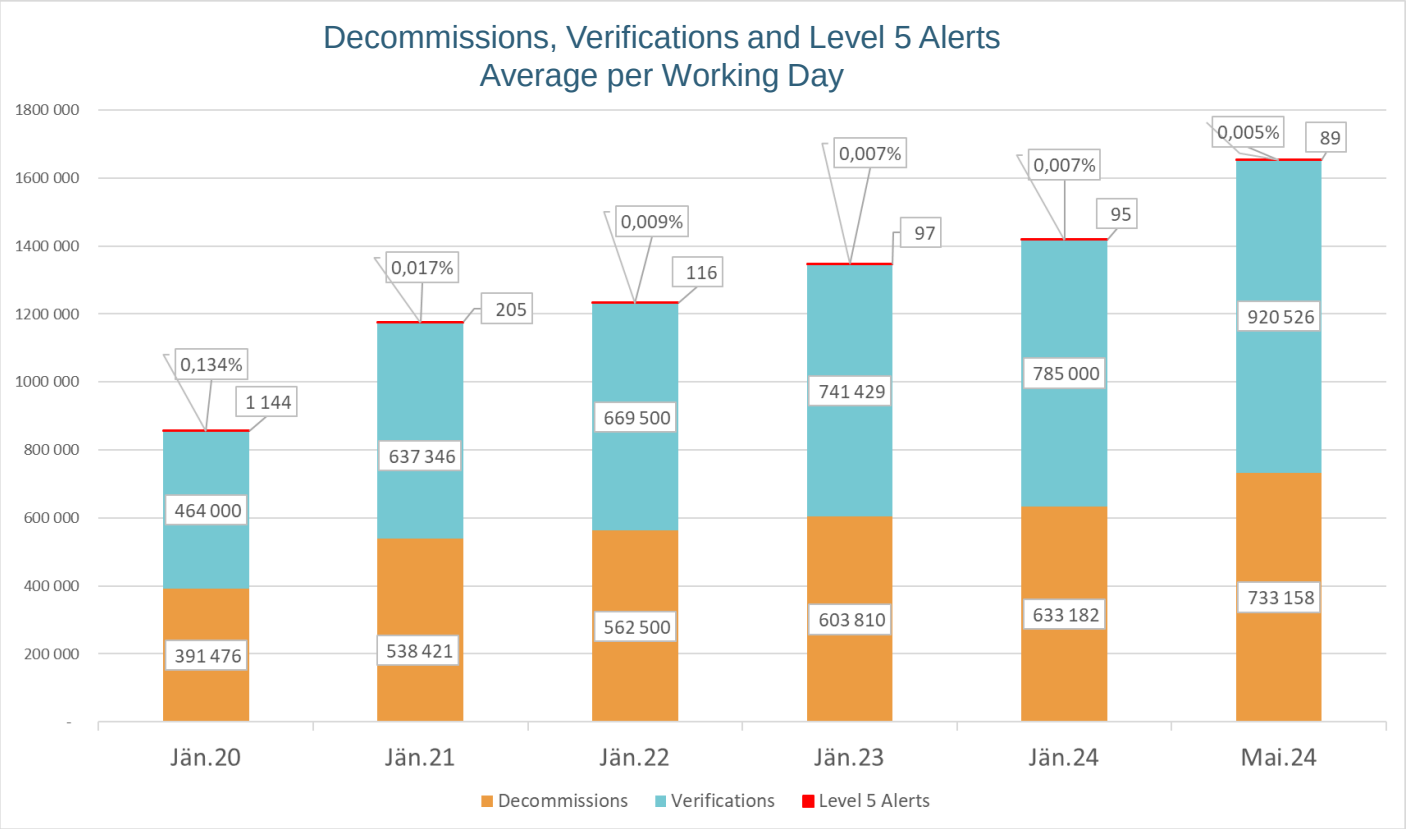
Alert Statistics – General Overview



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Alert Statistics – Alert Rates in Europe

RATE : TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS – PER COUNTRY - IN DECLINING ORDER

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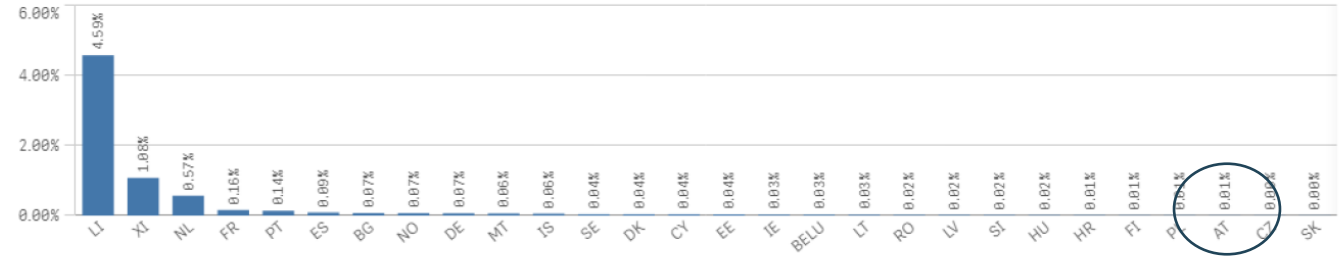
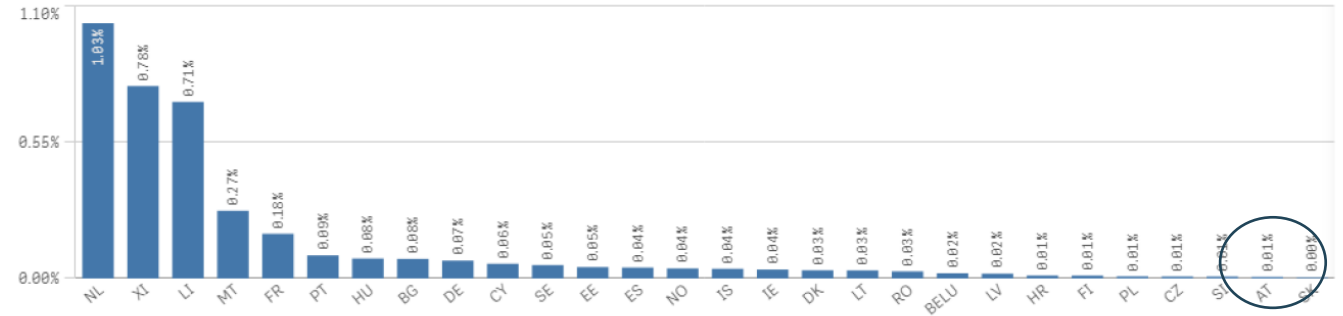
2024 - Week 15

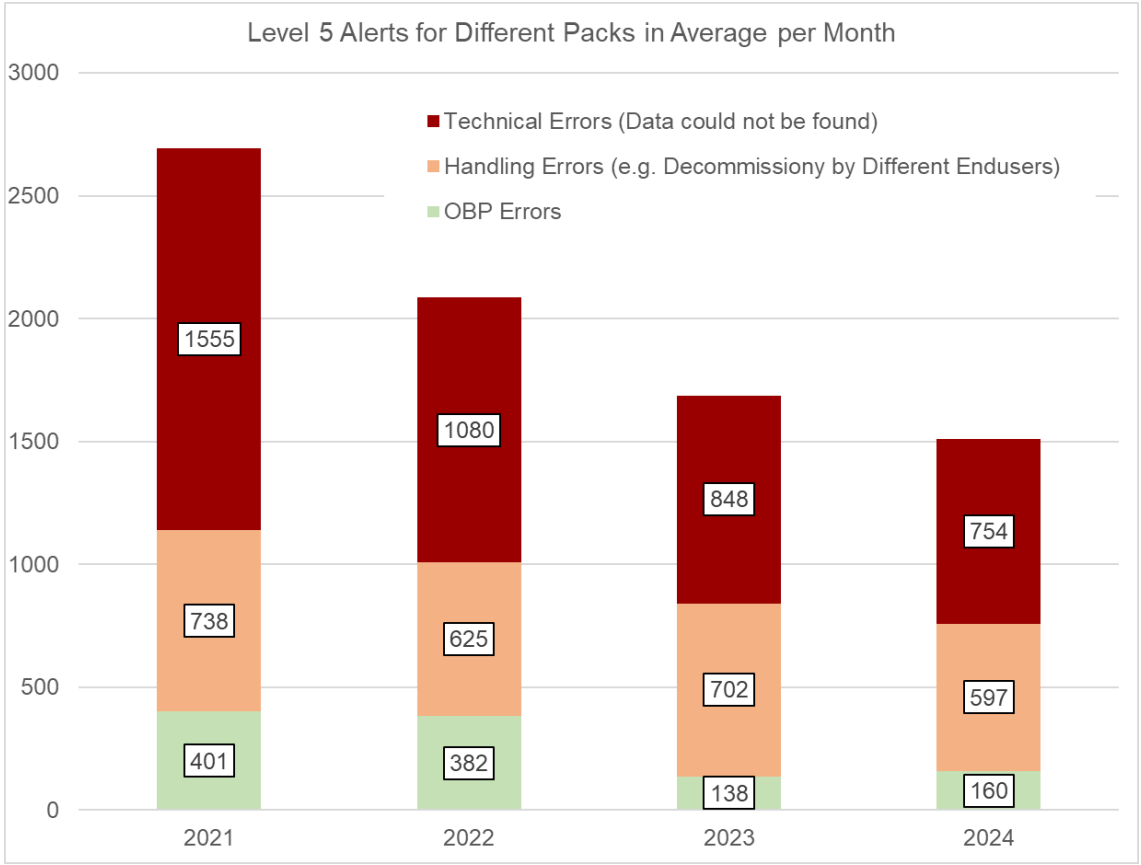


2024 - Week 17



Alert Rate incl. OBP-Alerts

Alert Statistics – Alerts per Category



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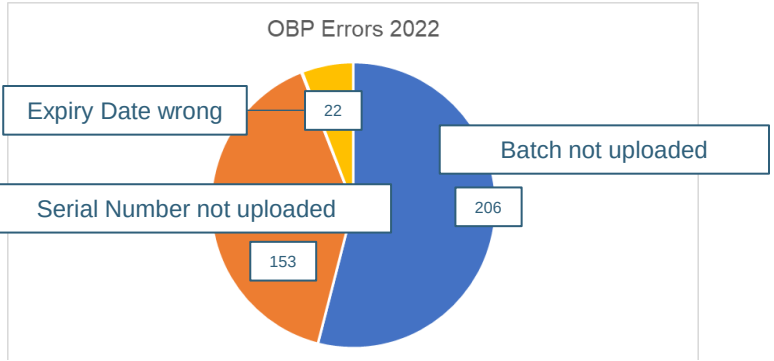
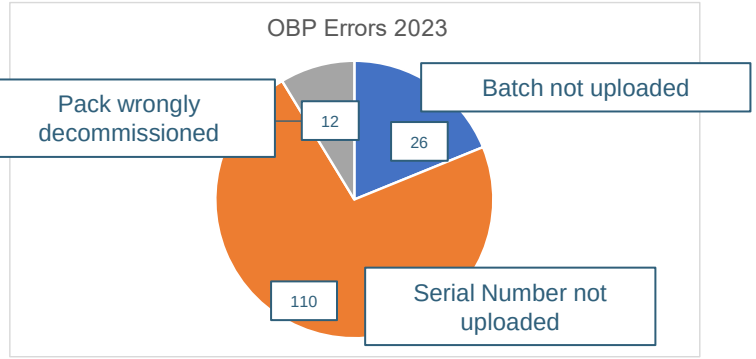
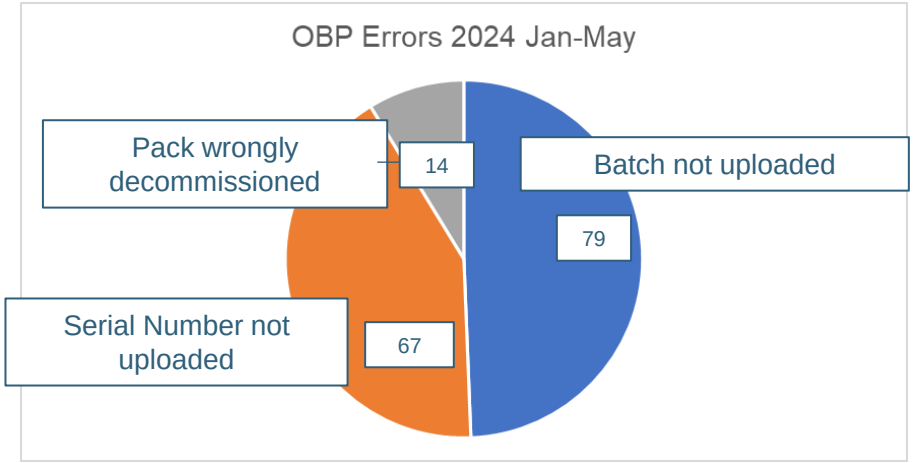
Alert Statistics – OBP Errors

Average Number of Packs per Month







OBP Errors

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Batch not uploaded - still delivered

- 18 Batches from 12 companies so far affected in 2024
- Number of alerts per incident from 3 to 150
- Various reasons given:
  - OBP transfer - product code not transferred
  - EU Hub certificate expired - not noticed
  - Contract manufacturer did not deliver data
  - Individual human error

→ Coordination with QP required

→ **Check the upload by verifying a pack**

OBP Errors

Austrian Medicines Verification System

Serial number not uploaded - batch partially uploaded

- "Blind passenger" packs
- 148 batches from 44 companies affected so far in 2024
- Number of affected serial numbers per batch from 1 to 15
- 3 companies reload affected serial numbers

OBP Errors

Austrian Medicines Verification System

Packs wrongly decommissioned

- Medicines Stock Out in Austria
- Replacement goods from another EU country
- Employee in helping country sets goods to "EXPORTED"

→ Note intermarket functionality

→ Interconnection of all NMVS via EU Hub

→ Decommission at the point of dispensation

→ "EXPORTED" exclusively to NON-EU

OBP Errors – AMVS Follow-up actions

Austrian Medicines Verification System

- NCA will be informed immediately if an entire batch is not uploaded or if a batch contains an increased number of "blind passengers“
- NCA will be informed in case of a probably not uploaded serial number if the OBP cannot confirm this error within 3 working days

→ NCA engagement enhanced

- If a batch is not uploaded, the full line wholesalers are also informed

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Start Phase Operations from 09.02.2020

Alerts are analyzed but not categorized as potential falsifications.

Affected packs are checked for integrity and authenticity and the verifying or dispensing location decides upon dispensing.

Disobedience of relevant duties by endusers, OBP, RPC and MAH will lead to sanctions by the respective competent bodies

Ongoing evaluation by representatives of AMVO, AMVS and BASG

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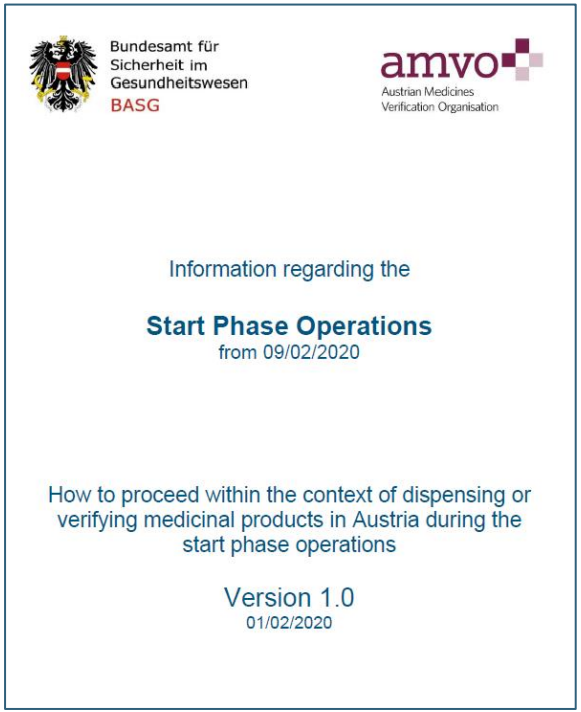
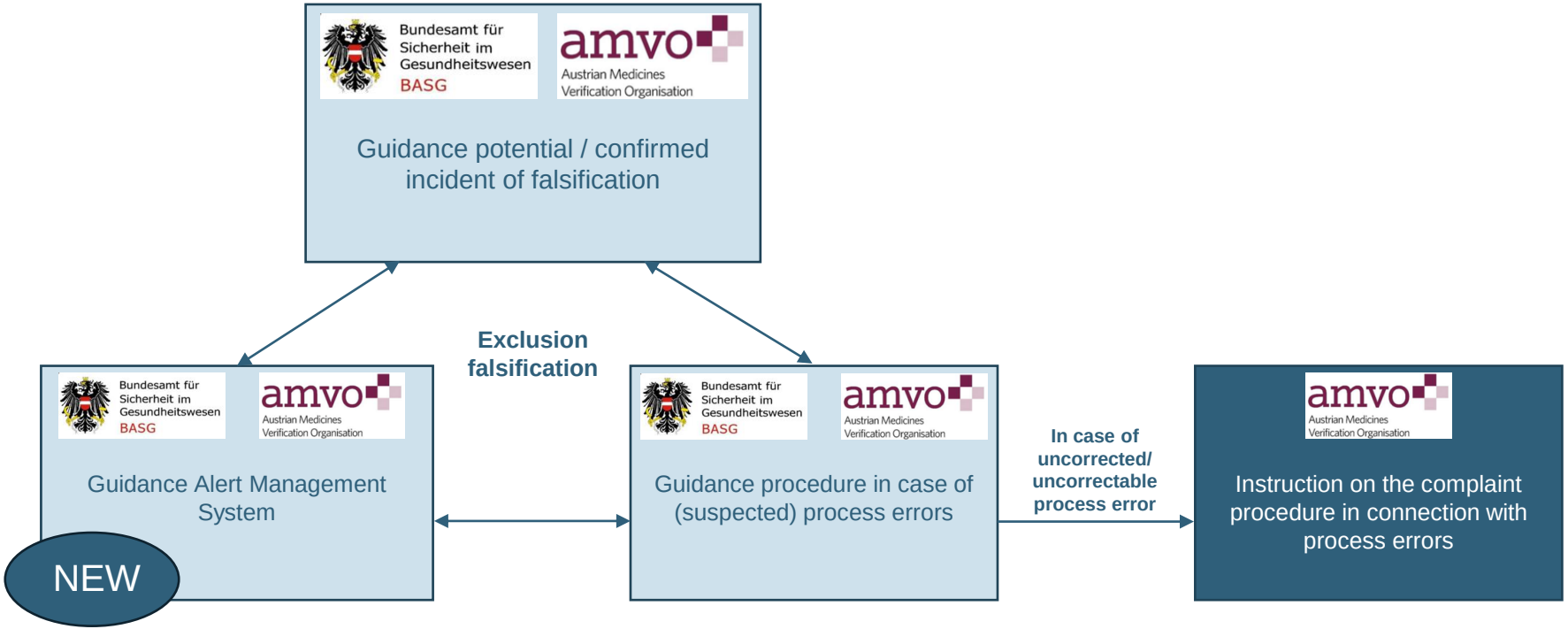


Processes around Potential Incidents of Falsification after Start Phase



Guidance Alert Management System

Austrian Medicines Verification System

- In final consultation with BASG and AMVO stakeholders.
- Supplement to the guideline potential / confirmed counterfeit case
- Strong recommendation from all stakeholders and the BASG to use the Alarm Management System
- Changes for pharmaceutical companies:
  - E-mail communication with AMVS and possibly BASG no longer necessary
  - Direct communication with all parties involved (AMVS, end user, BASG)
  - Status of an alarm always at a glance

Guidance Alert Management System

Austrian Medicines Verification System

- Processing of alerts by the pharmaceutical companies within 3 working days:
  - Who has caused the alert?
    - Pharmaceutical company (incl. contract manufacturer, pre-wholesaler,...)
    - End user
  - What is the reason for the alert? e.g:
    - Data incorrectly read in by the end user (e.g. serial number, batch too long / too short, etc.)
    - Handling error by the end user (e.g. double deactivation, deactivation of medical samples, etc)
    - Data not uploaded / incorrectly uploaded (e.g. batch / serial number not uploaded)
    - Accidental deactivation by OBP
  - If the pharmaceutical company has caused the alert:
    - Can the error be corrected? (e.g. uploading of the missing data)
    - If yes, by when has the error been rectified? (max. 10 calendar days)

Process around Potential Incident of Falsification after Start Phase

Duties of industry

Alert

Day 0

Feedback to AMVS /
Exclusion of suspicion of falsification
within 3 working days

Day 0

Correction of process errors
if possible
within 10 calendar days

Correction process errors: Uploading of missing data
Reverting of the decommission of mistakenly decommissioned packs

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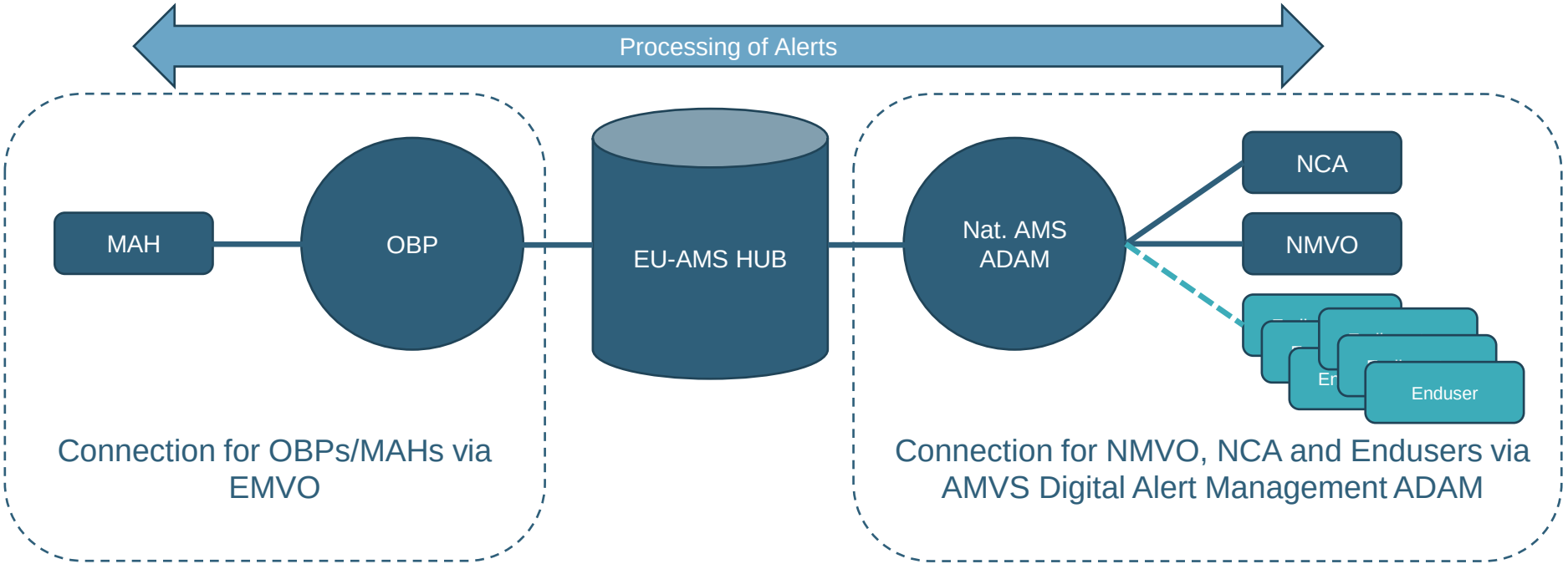
European Alert Management System (EAMS)

Austrian Medicines Verification System



European Alert Management System (EAMS) – Status in Europe

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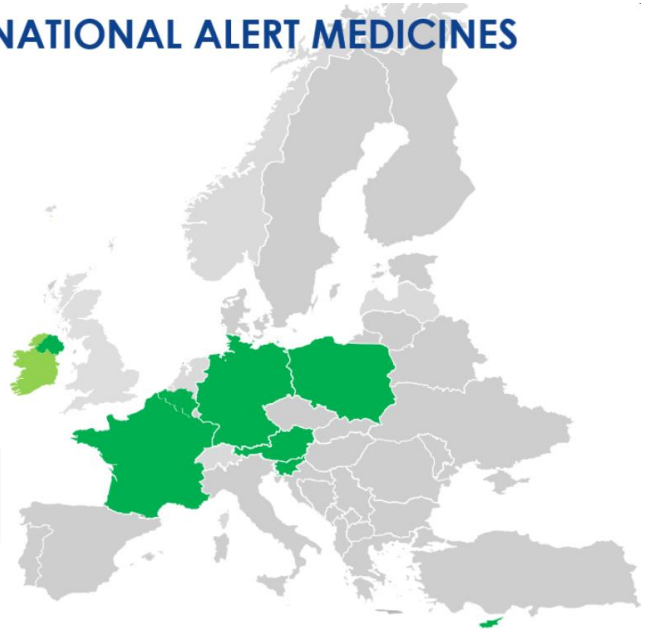
CONNECTION STATUS OF NATIONAL ALERT MEDICINES SYSTEMS (NAMS)

- Connected
  - AT, CY, DE, FR, SI, PL, NI, BE
- In progress
  - IE

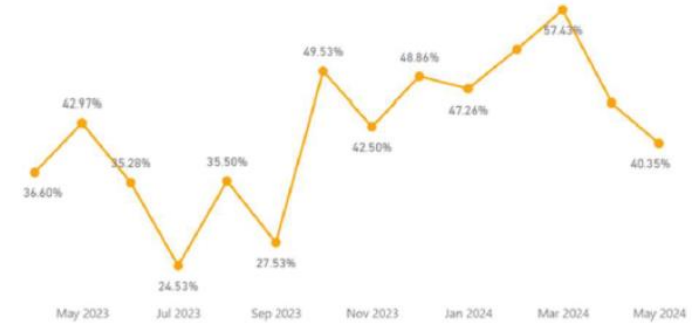


EAMS connected status (May 2024)

emvo

# of connected OBPs
196

Evolution of alerts related to products belonging to connected OBPs



This graph shows the amount and/or percentage of alerts raised in the indicated month(s) and associated to products belonging to OBPs connected to the AMS Hub (via the AMS Portal or via direct API connection).

Connected means that the Terms and Conditions in the AMS Portal were accepted.

European Alert Management System (EAMS) – Advantages for MAHs/OBPs

Austrian Medicines Verification System

- Free of charge
- User management, assignment of alerts and access levels
- Grouping / filtering of alerts by country
- Direct processing via the EAMS, no need for e-mail communication
- View the current status of an alert at any time
- Synchronized communication about alerts of all parties involved (OBP/MAH, end user, NMVO, NCA) and access to information (e.g. photo of DataMatrix code)
- Creation of rules and predefined feedback for certain constellations, thus reducing the number of alerts to be processed manually (see next slide)
- This ensures the same level of information for everyone involved when processing alerts

European Alert Management System (EAMS) – Advantages for MAHs/OBPs

Austrian Medicines Verification System

Possibilities to create rules per country and to process alarms automatically, e.g.

- all alerts whose serial number does not correspond to the length used
- all alerts generated by the OBP itself

European Alert Management System (EAMS) - Bearbeitung durch MAHs/OBPs

Key Points of Alert Processing

Overall Alert Status

Indicates the processing status of the alert

New – Under Investigation – Escalated – Closed

OBPs shall always set the Status to „Under Investigation“

AMVS (or NCA if required) will close the alert

OBP Investigation Status

shows the result of the OBP investigation

Root cause on my side / not on my side / pending

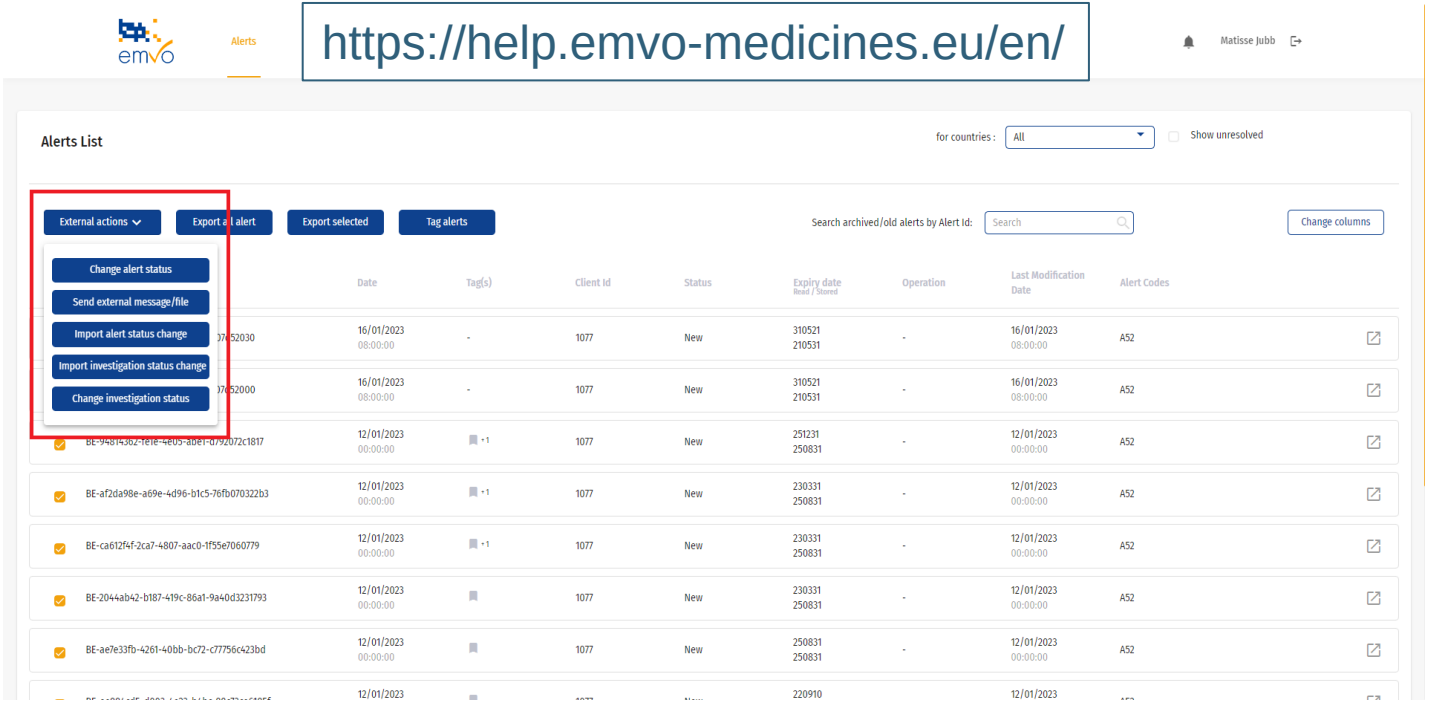
Comment (External message)

Provides details of the investigation - Possibility for Communication with NMVO / NCA / anonymized end user

European Alert Management System (EAMS) – Processing by MAHs/OBPs

Austrian Medicines Verification System

https://help.emvo-medicines.eu/en/



European Alert Management System (EAMS) – Processing by MAHs/OBPs

Austrian Medicines Verification System

https://help.emvo-medicines.eu/en/

AMVS Digital Alert Management (ADAM) - Advantages for NMVO, NCA and Endusers

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Enduser

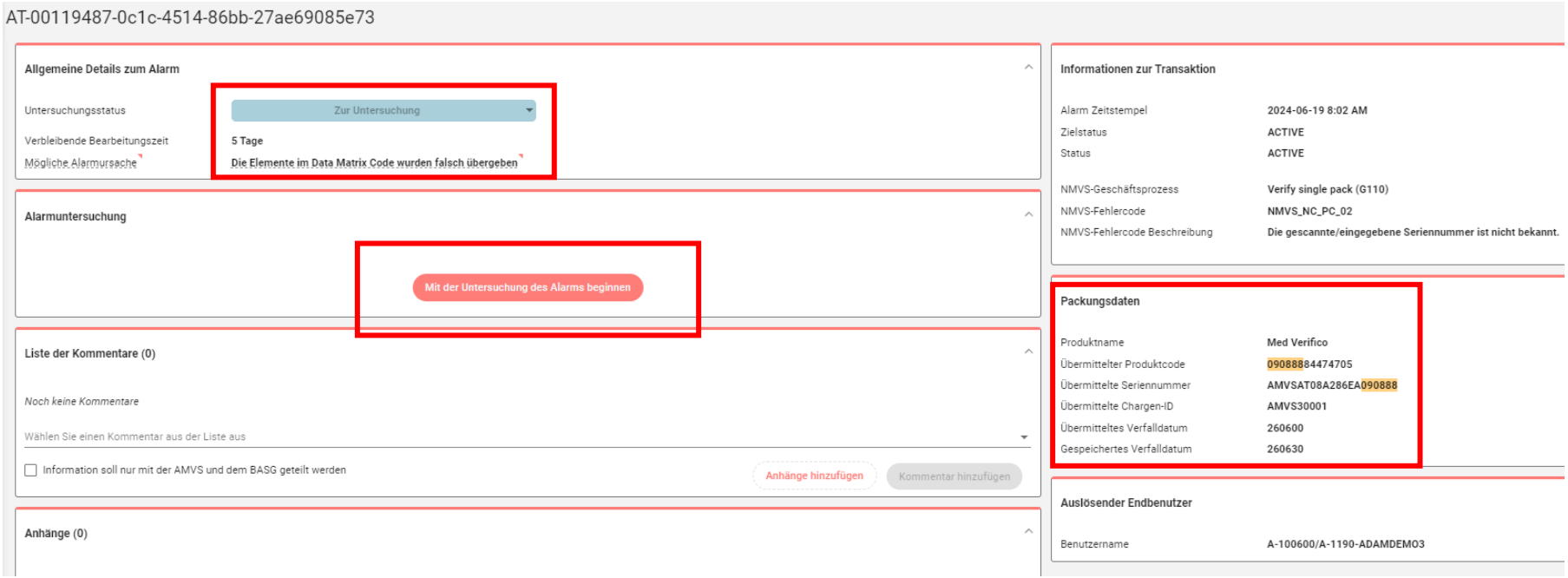
- Replaces email communication with NMVO and NCA
- Enduser can process alerts directly (or later) when generated – via web portal or API
- Alerts are classified and root cause is suggested – based on data collected

NMVO / NCA

- Several alerts can be grouped and processed simultaneously
- Remaining reaction time visible to endusers / NMVO / NCA
- Alerts are escalated directly to NCA when deadline is reached

AMVS Digital Alert Management (ADAM) Web Surface for Endusers

Austrian Medicines Verification System



AMVS Digital Alert Management (ADAM) Web Surface for Endusers

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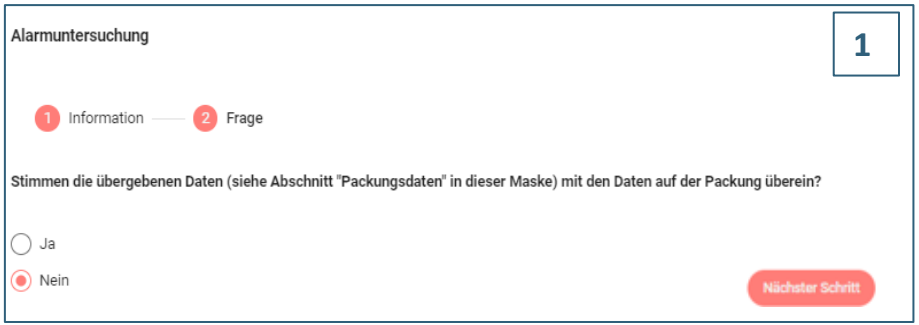

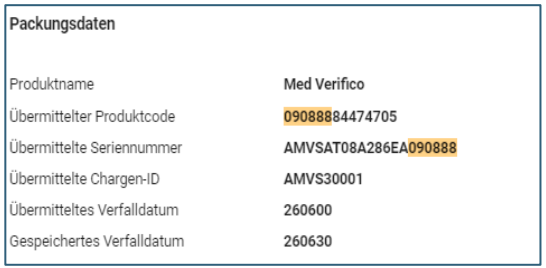

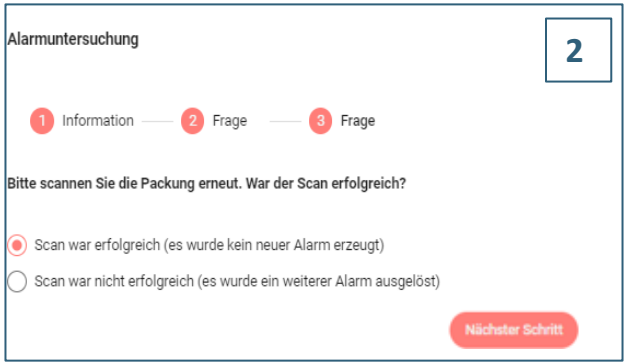

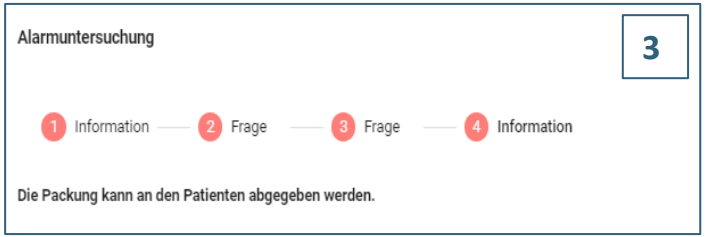

The roadmap of the European Alert Management System from an Austrian perspective

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2022

- Evaluation Alert Management Systems
- Decision for ADAM

2023

- Development ADAM
- Definition of end user workflows
- Roll out EAMS for industry
- Roll Out ADAM for AMVS, BASG

2024

- Development of end user workflows
- Roll out ADAM for end users (pharmacies, HAPOs, hospitals, wholesalers)

2025

- Enables anonymous end-to-end communication regarding alerts
- End users connected
- Industrial companies connected

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Five Years of Medicines Verification in Slovakia

Vienna, Jun 24th, 2024

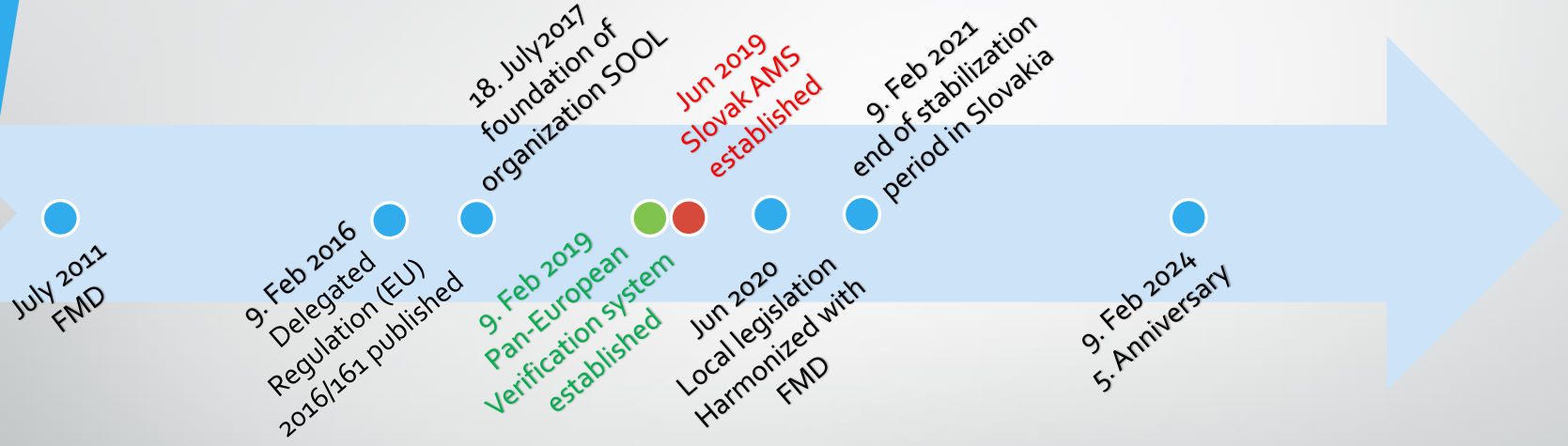
Roman Guba

Slovakia NMVO

Basic facts about Slovakia and medicines distribution system

- 5.500.000 inhabitants
- 2068 public pharmacies
- 43 hospital pharmacies
- 115 medicines wholesalers
- 110 millions Rx medicines packs are distributed yearly
- 3 main NCAs
  - Ministry of Health (main authority regarding harmonization of local legislation with EU legislation)
  - State institute of Drug Control = main NCA responsible for FMD area
  - Municipal offices (responsible to issue licenses to establish pharmaceutical services inside related territory)

FMD Milestones for Slovakia



Slovak Medicines Verification Organization - SOOL

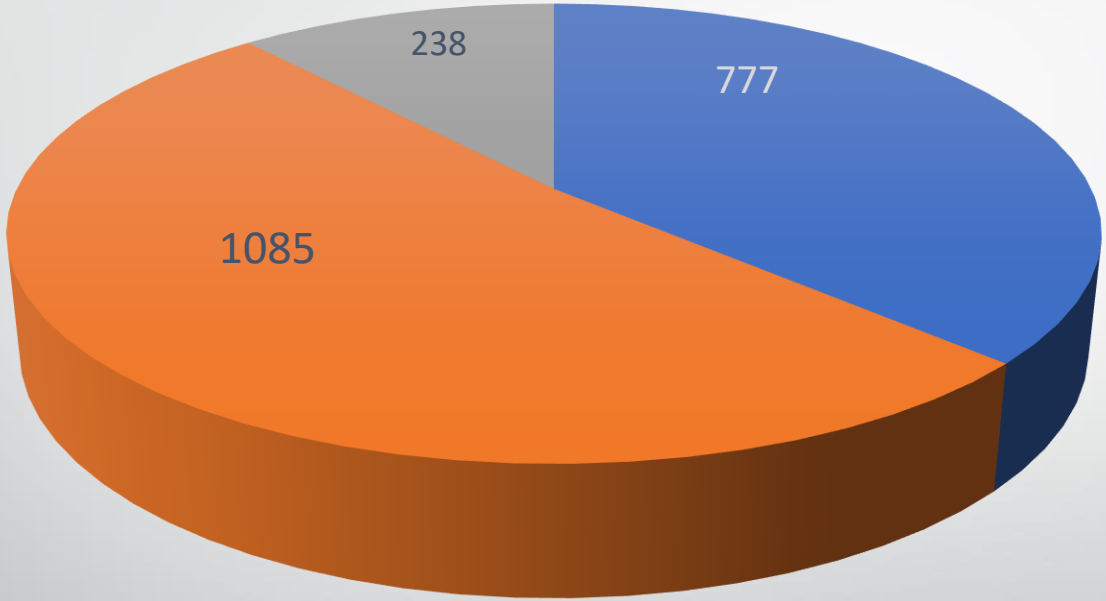
- Founded in 2017
  - AIFP (EFPIA), GENAS (Medicines For Europe), SIEK (PGEU),AVEL(GIRP)
- SOOL has 3 FTE
- ARVATO is software provider of BP system for Slovakia (contract signed in 2018)
- SOOL signed contract with EMVO regarding connection to EU-HUB
- SOOL established fix fee model regarding his funding by MAHs and signed contracts with pharma companies which represent around 300 MAHs
- SOOL established relation with end-users based on acceptance of "Terms and Conditions" statement by authorized users
- SOOL set-up internal processes and aligned them with common industry standards

Local Slovak AMS – key milestone of successful FMD implementation

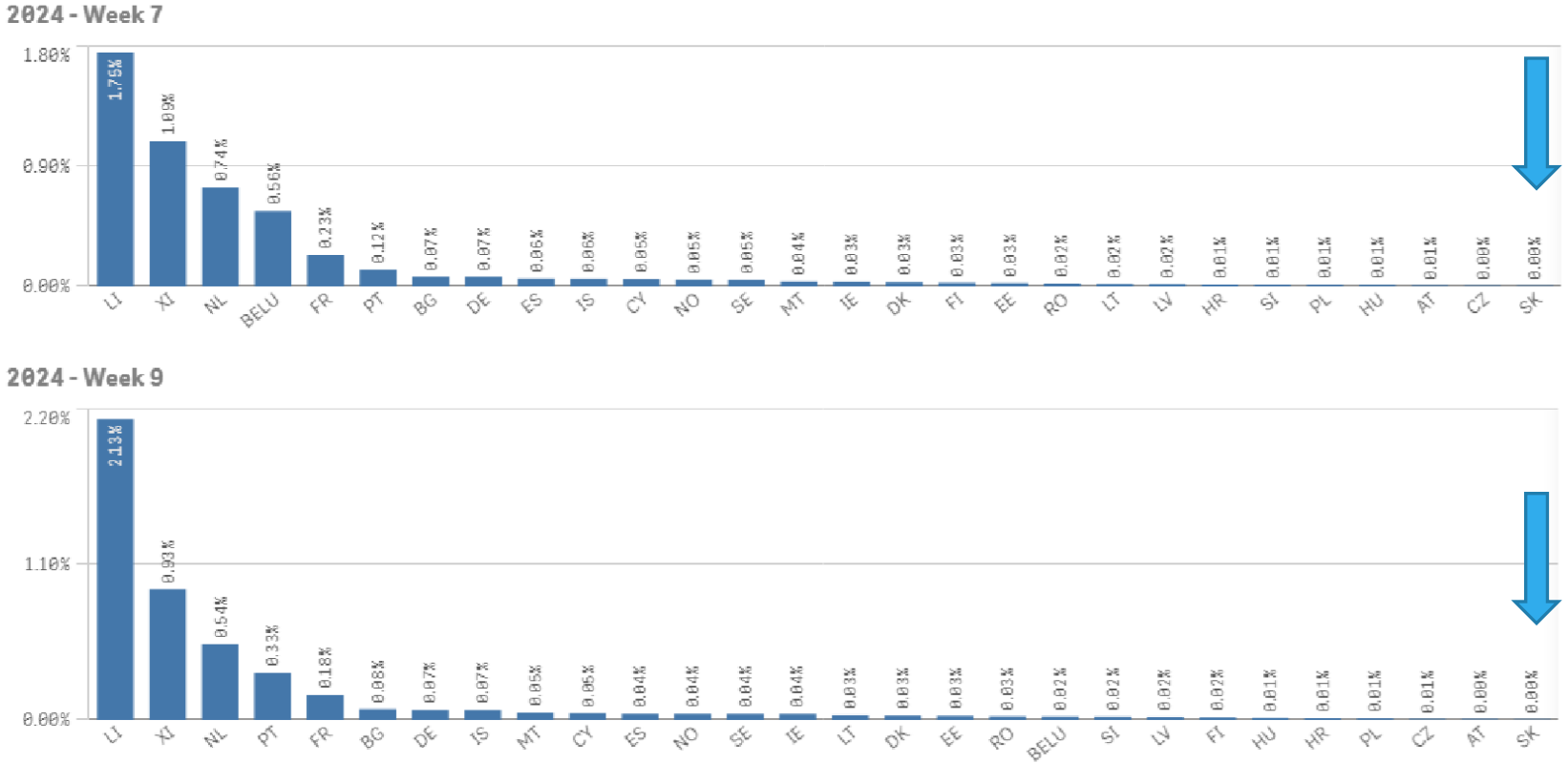
- SOOL and relevant NCA decided to develop local AMS in 2019
- It was implemented as an extension of existing NCA system used by all pharmacies and wholesalers for registration and reporting purposes
- All parties involved in alert investigation accepted this AMS including pharmacies, wholesalers ,MAHs and NCAs
- This tool support anonymous communication related to alert investigation between MAH and local NMVS users and significantly simplify investigation process for all involved parties
- Investigation process is governed by local guideline issued by Slovak Chamber of Pharmacies, SOOL and fully supported by NCA and almost fully in line with the EMVO Alert Investigation Document
- Local AMS fully reflect FMD requirements related to data protection and data ownership and data access
- Local NCA play clear role in investigation process defined and outlined in mentioned guideline and has decision power regarding serious suspicion incidents

Incidents per week – Slovakia users

Distribution of pharmacies according number of incidents



RATE : TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS – PER COUNTRY(*) – IN DECLINING ORDER



Notes:
- This overview reflects the total of level 5 alerts: A2, A24/A7, A3, A52, A68.
- Its sole purpose is to give an idea of the evolution of the alert rate in the EMVS per country

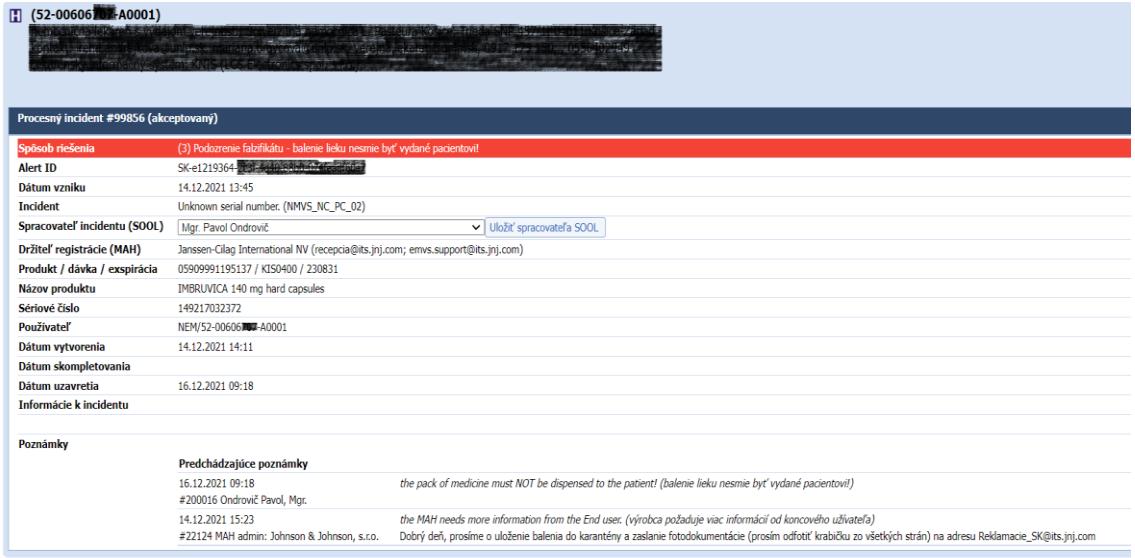
Collaboration SOOL and NCA

- Ministry of Health consulted SOOL regarding harmonization of local relevant legislation with FMD
  - Explicit statement in local legislation to be in compliance with FMD for all relevant members of medicine distribution chain
  - Explicit obligatory for wholesalers to deactivate UI in case of delivery Rx medicines pack to army, prisons, police and veterinary doctors
  - Definition of fines in case of non-compliance with FMD
- State Institute of Drug Controls (SUKL) is key NCA for SOOL with rights to inspect SOOL regarding compliance with FMD
  - Main consultant for AMS development and establishment and key user of this system
  - Bi-directional reporting schema established
  - SOOL is involved in education of SUKL inspectors
- Municipal offices (responsible to issue licenses to establish pharmaceutical services inside related territory)
  - Offer SOOL to use their common system for extension of this system to cover incident management (local AMS) and to use this system for validation of end-users of verification system
  - Opened to SOOL their communication channels towards all pharmacies

Key factors of successful implementation of FMD in Slovakia

- Highly supportive stakeholders of SOOL
- Strong collaboration with relevant NCAs
- Arvato CG intensive collaboration to maintain and develop verification system with high quality, and high effectiveness
- Stable and reliable operation of NMVS
- Strong cooperation with local software suppliers which are responsible for pharmacies/wholesalers IT systems
- EMVO and NMVOs community collaboration to keep stable and reliable interconnectivity through the EU-HUB and stability and reliability whole pan-European verification system

A case of falsified medicine



(52-00606[redacted]-A0001)

[redacted]

Procesný incident #99856 (akceptovaný)

Spôsob riešenia	(3) Podozrenie falzifikátu - balenie lieku nesmie byť vydané pacientovi!
Alert ID	SK-e1219364-[redacted]
Dátum vzniku	14.12.2021 13:45
Incident	Unknown serial number. (NMVS_NC_PC_02)
Spracovateľ incidentu (SOOL)	Mgr. Pavol Ondrovič — Uložiť spracovateľa SOOL
Držiteľ registrácie (MAH)	Janssen-Cilag International NV (recepcia@its.jnj.com; emvs.support@its.jnj.com)
Produkt / dávka / exspirácia	05909991195137 / KIS0400 / 230831
Názov produktu	IMBRUVICA 140 mg hard capsules
Sériové číslo	149217032372
Používateľ	NEM/52-00606[redacted]-A0001
Dátum vytvorenia	14.12.2021 14:11
Dátum skompletovania	
Dátum uzavretia	16.12.2021 09:18
Informácie k incidentu	

Poznámky

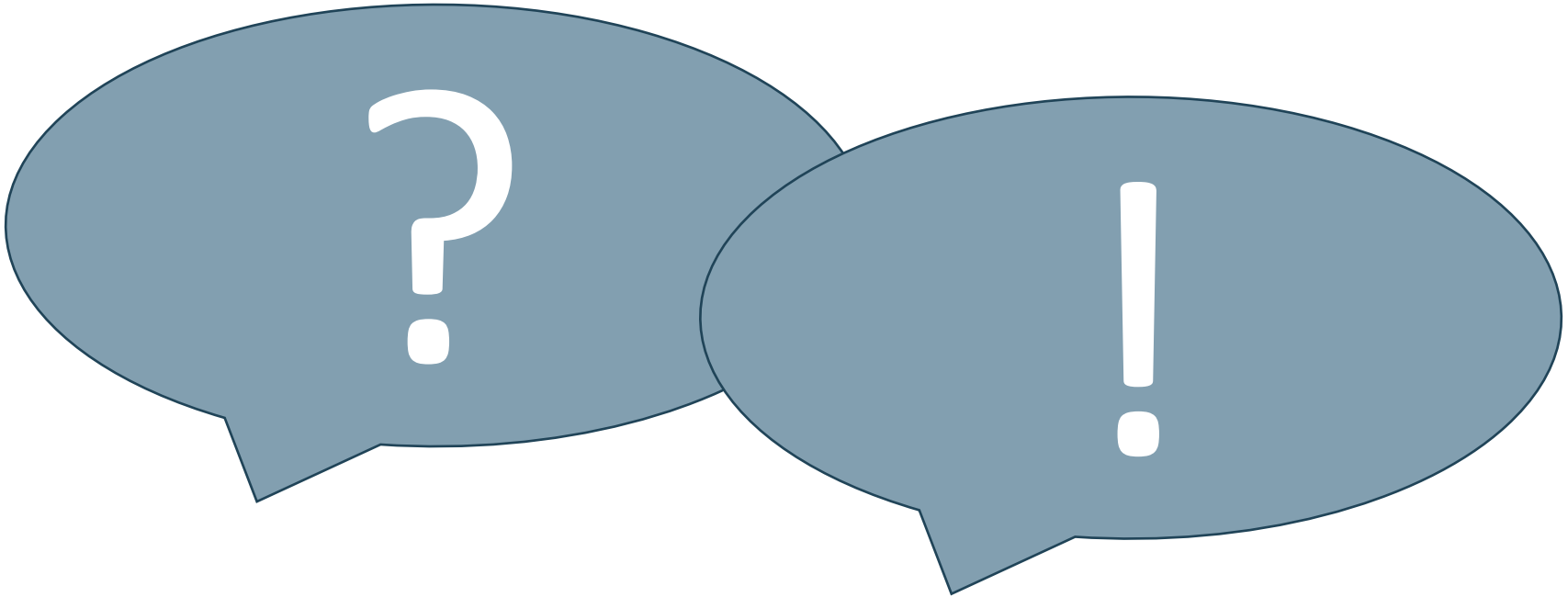
Predchádzajúce poznámky

16.12.2021 09:18 #200016 Ondrovič Pavol, Mgr.	*the pack of medicine must NOT be dispensed to the patient! (balenie lieku nesmie byť vydané pacientovi!)*
14.12.2021 15:23 #22124 MAH admin: Johnson & Johnson, s.r.o.	*the MAH needs more information from the End user. (výrobca požaduje viac informácií od koncového užívateľa)* Dobrý deň, prosíme o uloženie balenia do karantény a zaslanie fotodokumentácie (prosím odfotiť krabičku zo všetkých strán) na adresu Reklamacie_SK@its.jnj.com

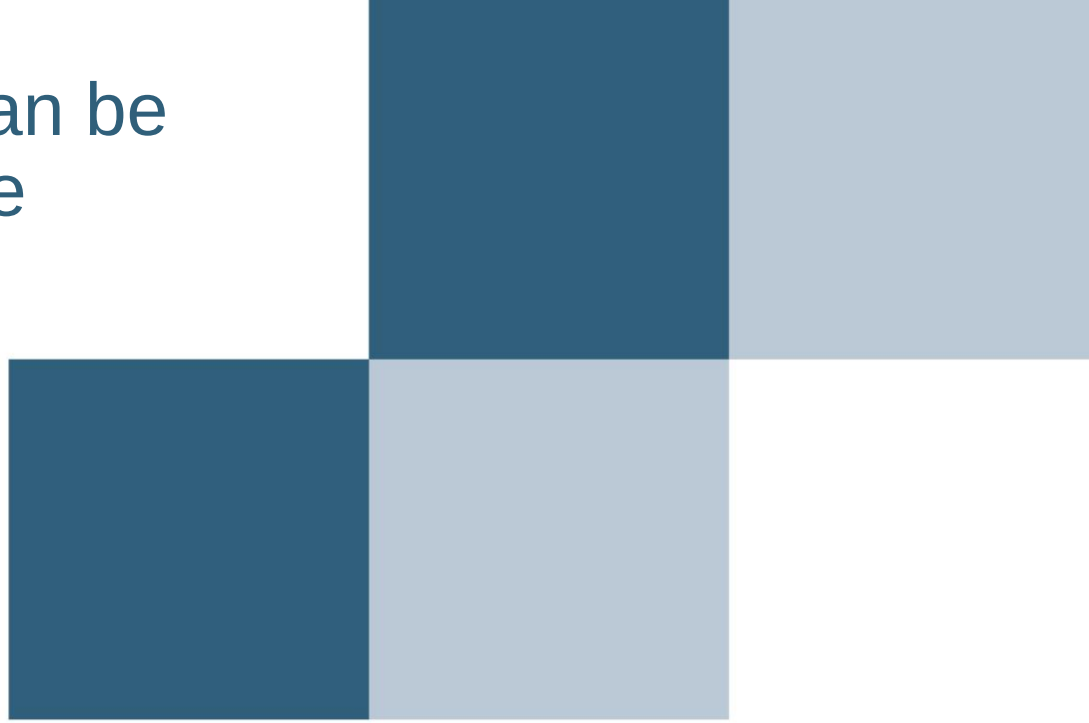
- Here is a sample of an incident from our SK AMS, where the falsification of the given packs by the manufacturer and the NCA was confirmed.
- Thanks to early identification, the packs were seized and sent for expert examination. Relevant MAH reacted very promptly and escalated the incident to the NCA after consultation with the NMVO.
- NCA immediately sent an inspection to the end user to check and secure the given packs.

Questions and Discussions

Austrian Medicines Verification System



Current information can be found on our webpage https://www.amvs-medicines.at/en/ as well as our LinkedIn channel.



You are always welcome to contact us under office@amvs-medicines.at or +43 1 9969499 0

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