

# Information Event Pharmaceutical Companies



Livestream Event

14.06.2023



# Agenda

- AMVS Organisation, Status Agreements and Changes Fee Model
- FAQs Coding
- Alert Statistics and Sources of Error
- Validation and Change Control
- New System Features
- Status Start Phase Operations and European Alert Management System

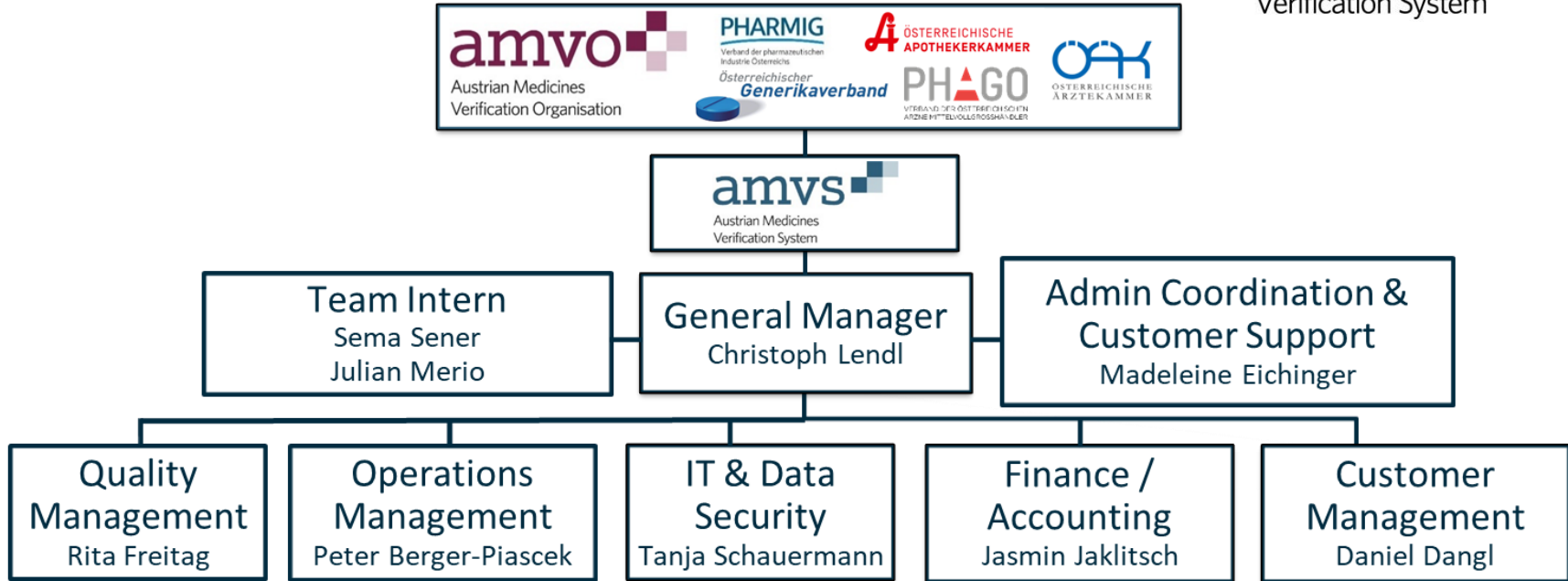
# Agenda

- **AMVS Organisation, Status Agreements and Changes Fee Model**
- FAQs Coding
- Alert Statistics and Sources of Error
- Validation and Change Control
- New System Features
- Status Start Phase Operations and European Alert Management System

# AMVS Organisation



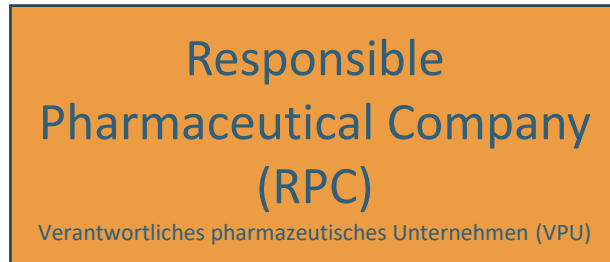
Austrian Medicines  
Verification System



# Contractual Relations – Responsible Pharmaceutical Companies



Declaration of Accession  
Accession- and Service Agreement



Status: 09.05.2023

# Operational Fees

## NEW Fee Model from 2024



### Fixed Turnover-based Part

- Reduction of the fee by 10% for all user groups

### Variable Volume-based Part

- Reduction of the fee by 0,001€ per serial number for the fee class  $\geq$  2.000.001 serial numbers

### Invoicing

- Reduction of number of invoices per year

# Operational Fees

## NEW Fee Model from 2024



Austrian Medicines  
Verification System

### Fixed Turnover based Part

<b>Turnover € / User p.a.</b>	<b>Fee 2022-2023 € / User p.a.</b>	<b>Fee NEW from 2024 € / User p.a.</b>
< 100k	400	360
100k-1.5 Mio	1 200	1 080
1.5-3 Mio	2 400	2 160
3-10 Mio	4 000	3 600
10-20 Mio	6 000	5 400
20-30 Mio	12 000	10 800
30-50 Mio	20 000	18 000
50-70 Mio	28 000	25 200
70-100 Mio	36 000	32 400
100-150 Mio	44 000	39 600
150-200 Mio	52 000	46 800
200-250 Mio	60 000	54 000
> 250 Mio	68 000	61 200

# Operational Fee NEW Fee Model from 2024

## Variable Volume-based Part

<b>Price-Quantity Scale p.a.</b>	<b>€/serial number 2022-2023</b>	<b>€/serial number NEW from 2024</b>
≤ 2.000.000	0,007	0,007
≥ 2.000.001	0,004	0,003

Number of uploaded serial numbers based on AMVSystem



# Operational Fee NEW Fee Model from 2024

Invoicing from 2024:  
Only 3 invoices / year

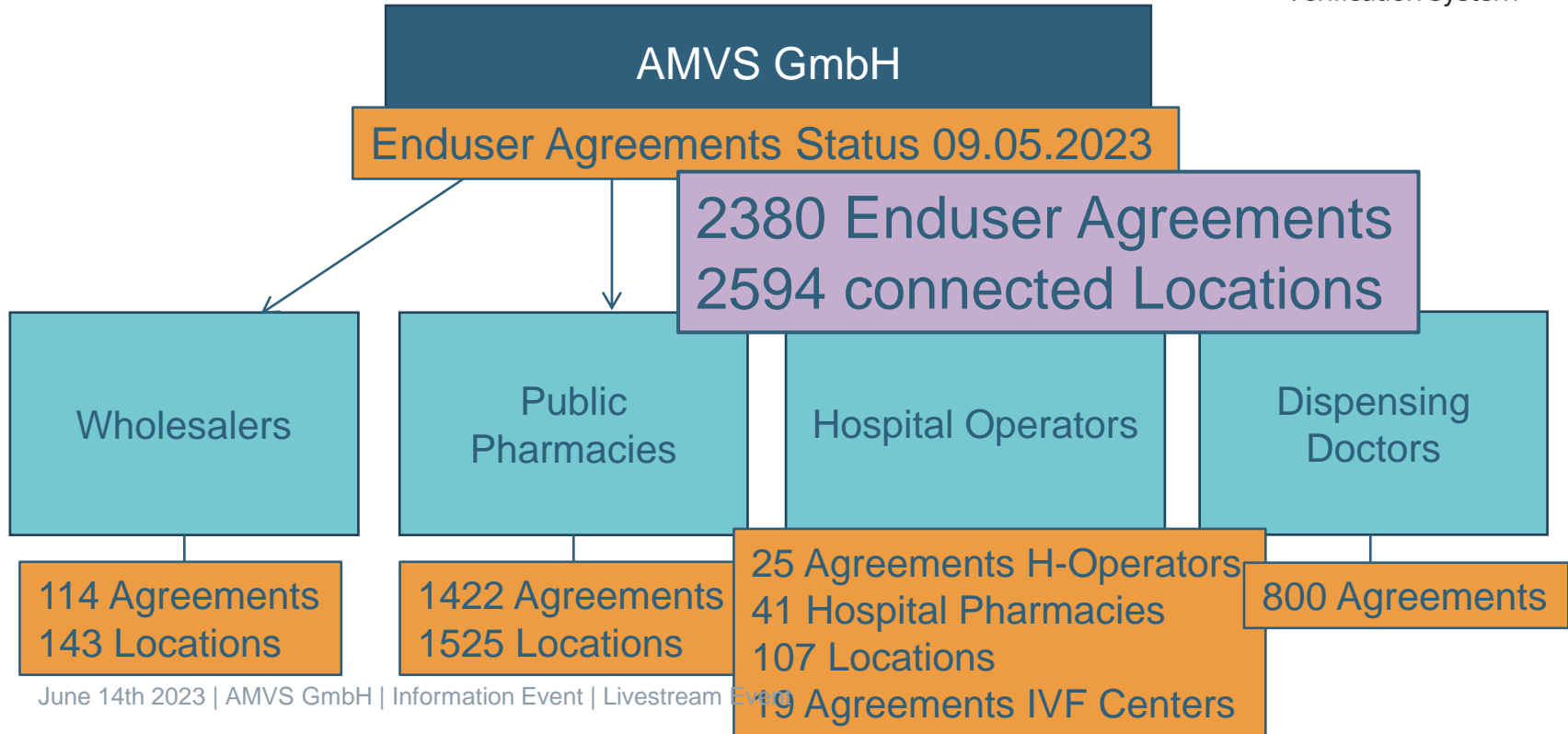
Fixed Turnover based Part:  
Turnover Declaration until 31st January

Invoicing until 28th February

Variable Volume-based Part:  
Uploads January - June  
Uploads July - December  
Payment Deadline 30 Days

Invoicing until 31st July  
Invoicing until 31st January

# Contractual Relations – Endusers



# Agenda

- AMVS Organisation, Status Agreements and Changes Fee Model
- **FAQs Coding**
- Alert Statistics and Sources of Error
- Validation and Change Control
- New System Features
- Status Start Phase Operations and European Alert Management System

# Coding Rules for Austria



## Coding Rules for Austria Version 4.0 published in November 2020

German Version:

<https://amvs-medicines.at/FileDownload/4418>

English Version:

<https://amvs-medicines.at/FileDownload/4419>

# FAQs Coding

Do I have to use an NTIN as product code?

Yes, if it is a single market pack for Austria.

For multi market packs a GTIN can be used as well as an NTIN from another country (e.g., Germany)

## What else do I have to consider for multi market packs?

- Linkage of PZN and product code via
  - Upload of PZN as NHRN (Austrian PZN: 7 digits incl. its own check digit)
  - Storage of product code in the „Warenverzeichnis“
- Upload into all markets where the product is marketed

# FAQs Coding

## Do I 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
- The June EU Hub release will implement a check for NHRN and it will not be possible to create new Master Data for Austria with a wrongly created PZN

# FAQs Coding

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



# FAQs Coding

## Are there any other news regarding coding?

- **Reminder: new provisions for expiry date format**
  - 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: 31<sup>st</sup> December 2025**

currently allowed:	251200 and 251231
from 2025:	251231

# Agenda

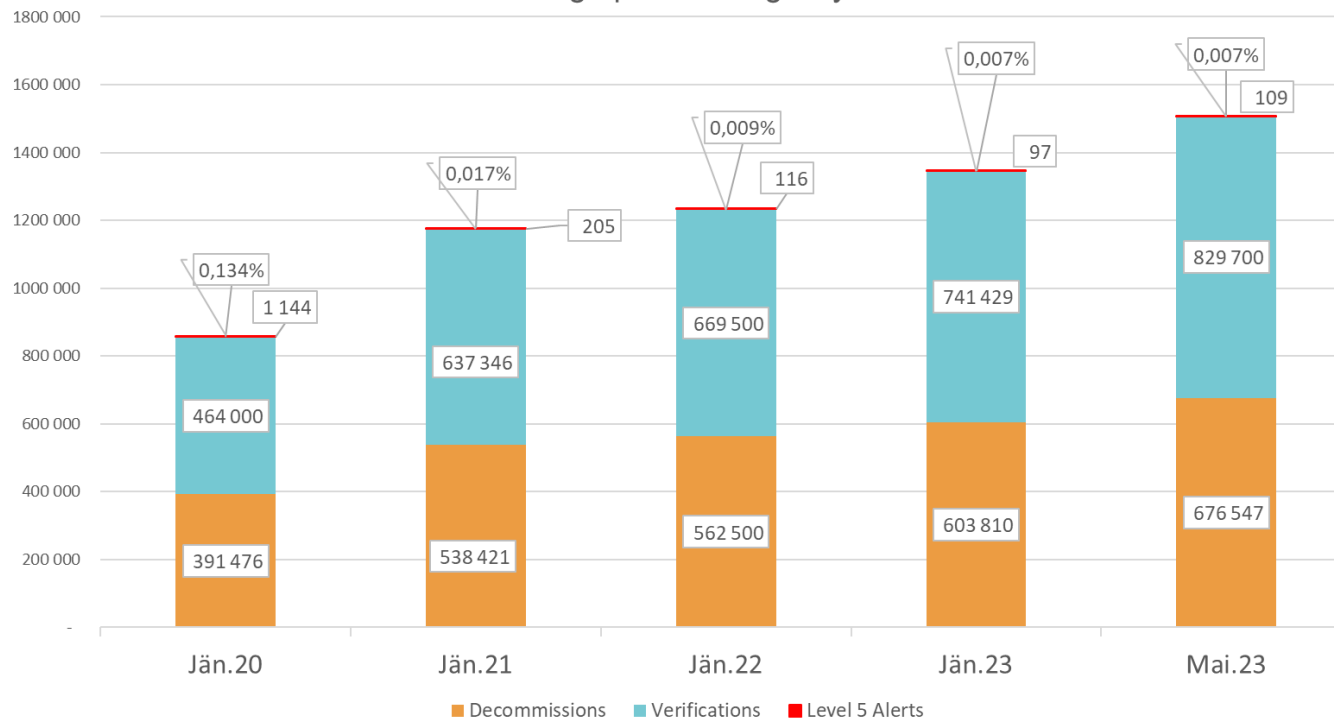
- AMVS Organisation, Status Agreements and Changes Fee Model
- FAQs Coding
- **Alert Statistics and Sources of Error**
- Validation and Change Control
- New System Features
- Status Start Phase Operations and European Alert Management System

# Alert Statistics – General Overview



Austrian Medicines  
Verification System

Decommissions, Verifications and Level 5 Alerts  
Average per working Day

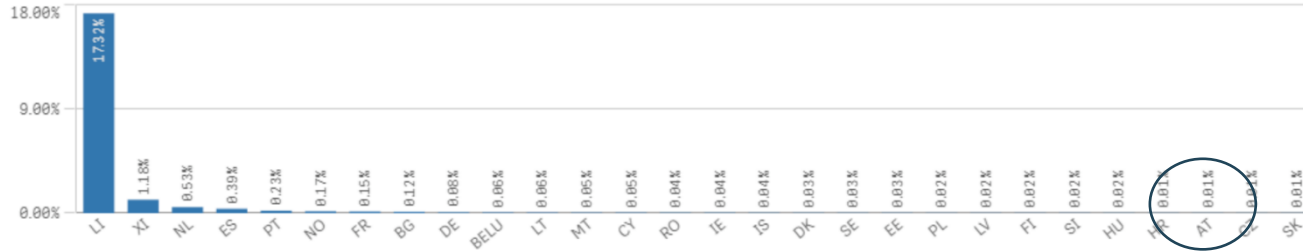


# Alert Statistics – Alert Rates in Europe

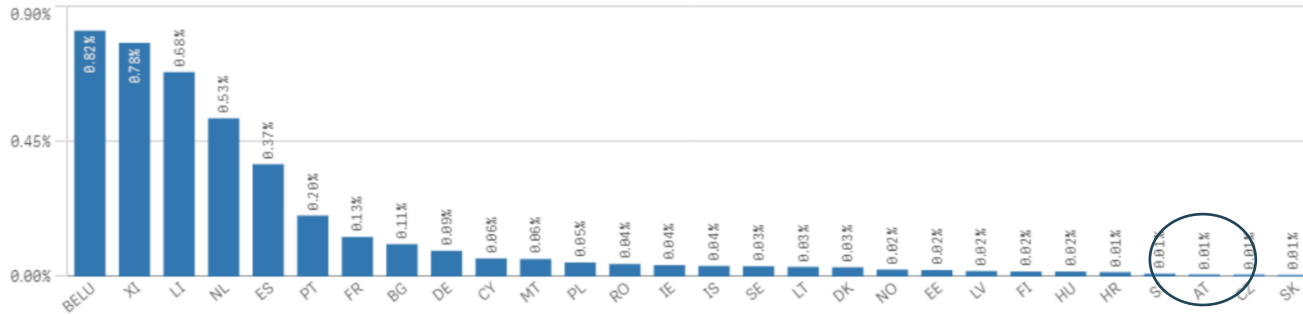


RATE : TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS – PER COUNTRY – IN DECLINING ORDER

2023 - Week 15



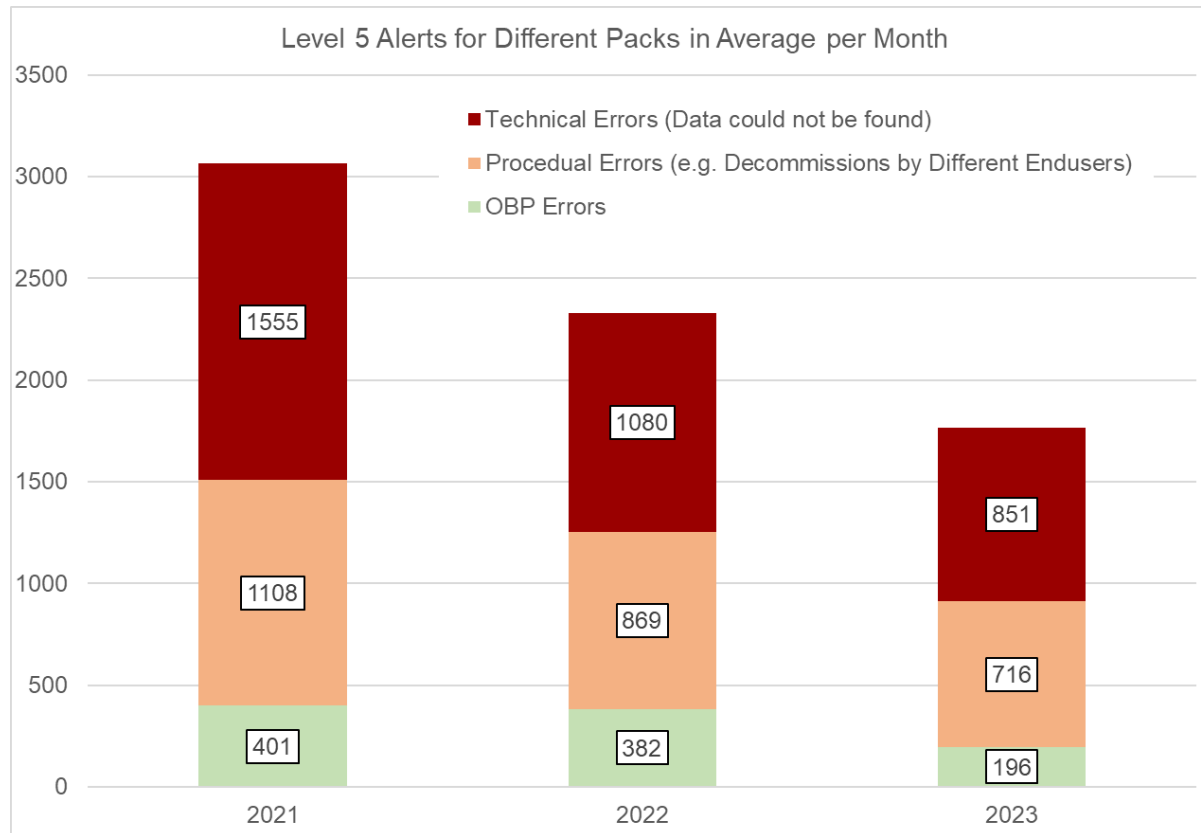
2023 - Week 17



# Alert Statistics – Alerts per Category



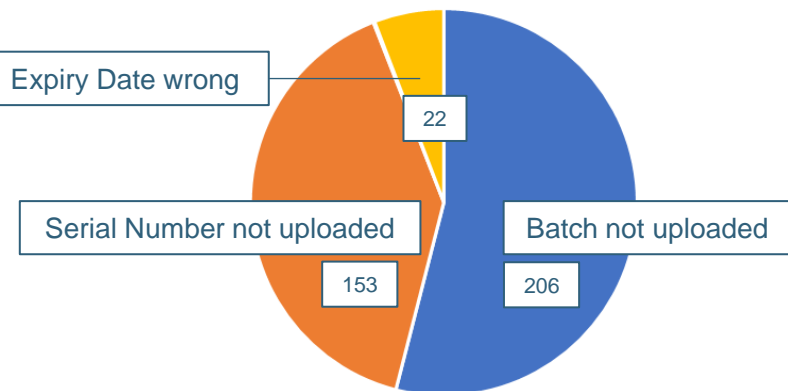
Austrian Medicines  
Verification System



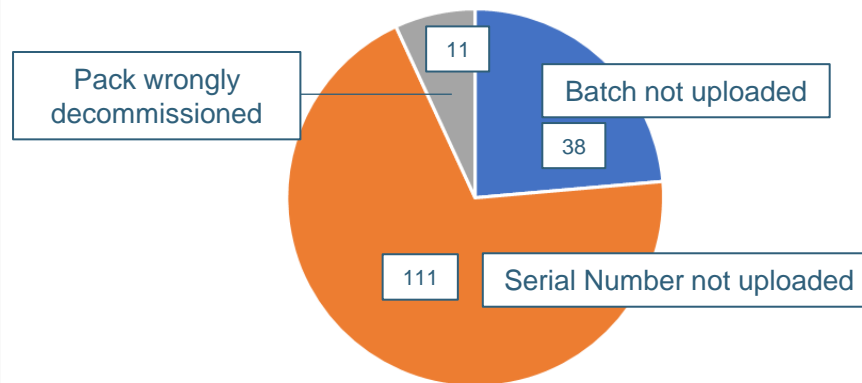
# Alert Statistics – OBP Errors

## Average Number of Packs per Month

OBP Errors 2022



OBP Errors 2023 Jan - May



# OBP Errors – Examples

## Batch not uploaded after MAH Transfer:

### Case 1 March 2022:

„old“ MAH did not initiate transfer of product at EU Hub, „new“ MAH released two batches on the market

400 packs causing alerts in almost three weeks, no contact with „new“ MAH for 2 weeks

### Case 2 August 2022:

Pre-Wholesaler ignores advise of „new“ MAH not to deliver packs

1200 packs causing alerts in 4 days

# OBP Errors – Examples

## Batch not uploaded, no check in warehouse

### Case 1 March and December 2022

no warehouse check implemented, in total 3 batches affected, 500 packs causing alerts within 3 - 5 days

### Case 2 December 2022

no warehouse check (forgotten to implement due to change of responsibilities), 85 alerts within 2 days



# OBP Errors – Examples

## Batch incompletely uploaded

### Case 1 November 2022:

Batch uploaded in several data sets, one was forgotten  
850 packs causing alerts within 2 days

### Case 2 ongoing since January 2023:

Batch incompletely uploaded due to issues on packaging line – no correction possible  
more than 200 packs causing alerts so far

# OBP Errors – Examples

## Batch uploaded with wrong expiry date

### Case April 2022

OBP uploads batch with wrong expiry date (wrong year)

Pre-Wholesaler detects wrong expiry dates and informs MAH several times for two weeks

Nevertheless Austrian entity of MAH decides to deliver product to endusers

250 alerts within 2 days

# OBP Errors – Examples

## Packs accidentally decommissioned

Case ongoing since April 2023

Packs decommissioned accidentally as Art.23 packs by warehouse using MAH's OBP credentials

OBP takes two weeks to confirm error

more than 50 packs causing alerts so far, approx. 200 expected

# OBP Errors – AMVS Follow-up actions

- NCA is informed immediately if a whole batch is affected (or large number of packs within a batch)
  - NCA is informed if OBP cannot confirm error within 3 working days if a serial number seems to be not uploaded
- NCA engagement enhanced
- In case of whole batch affected (or large number of packs within a batch) wholesalers are informed as well

# Agenda

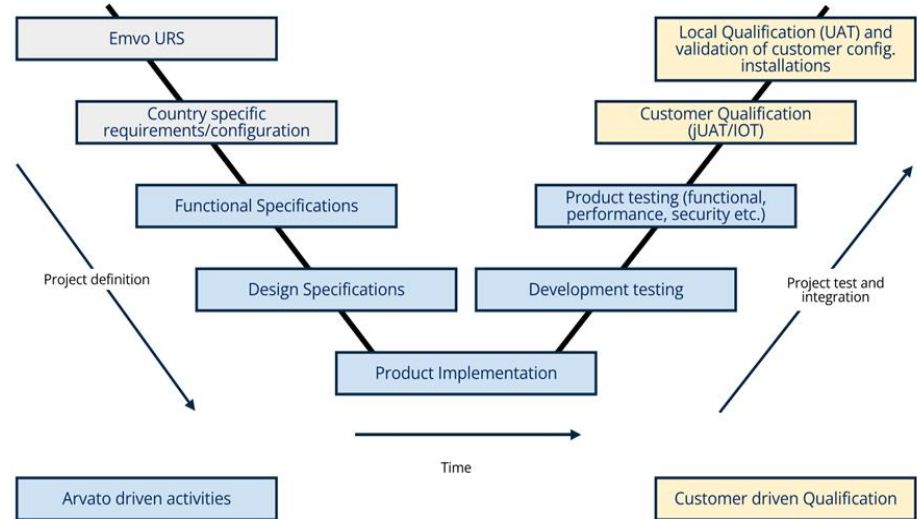
- AMVS Organisation, Status Agreements and Changes Fee Model
- FAQs Coding
- Alert Statistics and Sources of Error
- **Validation and Change Control**
- New System Features
- Status Start Phase Operations and European Alert Management System

# Change Control

- **Each** change requested (CR) to the NMVS is reviewed and approved within the Arvato Customer Group and SolidSoft Reply Customer Group/EMVO CG.
  - Evaluated if compliant with DR and EMVS URS
  - Controlled and Proceduralized Process (CG Change Advisory Boards CAB, EU Change Control Board EU CCB)
  - Interlinked with Validation, Release and Deployment processes

# Validation - Based on GAMP5

- **Each** change request is tested/validated.
  - ✓ Vendor Testing
    - (e.g functional, performance, security testing)
  - ✓ Customer Testing
    - (joint NMVO approach, Inter Operability Testing)
      - ✓ Local activities
- Validation activities done-> Release & Deployment Process takes over



## ❖ Rollout of a new Release

# Agenda

- AMVS Organisation, Status Agreements and Changes Fee Model
- FAQs Coding
- Alert Statistics and Sources of Error
- Validation and Change Control
- **New System Features**
- Status Start Phase Operations and European Alert Management System



# Release 3.0 AMVSystem

Scanner configuration check (Autumn 2023)

Dynamic character and uppercase/lowercase swap in case of:

- serial number not found (#A3)
- batch not found (#A2)
- serial number found in another batch (#A68)

If the scanner is misconfigured and a pack is scanned (SN: 123YBA45 is printed on the pack, scanner reads 123ZBA45) the Z is exchanged with Y and if the pack is found in the national system, the transaction is successful and no alert is raised.

**Enduser:** receives an additional returncode to inform about the misconfigured scanner

**OBP:** receives no information

**Avoidance of alarms**

# Release 1.13 European HUB

NHRN check (June 2023)

When creating product master data entry of NHRN (PZN) is mandatory in Austria

To avoid entry of wrong NHRN to Austrian products, a check is implemented when creating product master data on the HUB that calculates if the entered NHRN is correct.

**Avoidance of wrong NHRN in product master data**

# Release 1.13 European HUB

## NHRN check (June 2023) Calculation

The PZN (=NHRN) has 6 digits + 1 check digit.

The calculation is (*i.e. for 447470*):

$$1^{\text{st}} \text{ digit} * 2 = \text{value 1} = 8$$

$$2^{\text{nd}} \text{ digit} * 3 = \text{value 2} = 12$$

$$3^{\text{rd}} \text{ digit} * 4 = \text{value 3} = 28$$

$$4^{\text{th}} \text{ digit} * 5 = \text{value 4} = 20$$

$$5^{\text{th}} \text{ digit} * 6 = \text{value 5} = 42$$

$$6^{\text{th}} \text{ digit} * 7 = \text{value 6} = 0$$

$$\text{Intermediate Checksum} = \text{value 1} + \text{value 2} + \text{value 3} + \text{value 4} + \text{value 5} + \text{value 6} = 110$$

$$\text{Check digit} = \text{MODULO 11 of Intermediate Checksum} = 0 \text{ (} 110/11 \text{ remainder} = 0 \text{)}$$

$$\text{NHRN 6 digits} + 1 \text{ check digit} = 4474700$$

If the remainder is 10, the number is **not** assigned by FCIO.

# Agenda

- AMVS Organisation, Status Agreements and Changes Fee Model
- FAQs Coding
- Alert Statistics and Sources of Error
- Validation and Change Control
- New System Features
- **Status Start Phase Operations and European Alert Management System**

# 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



Austrian Medicines  
Verification System



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
BASG



Austrian Medicines  
Verification Organisation

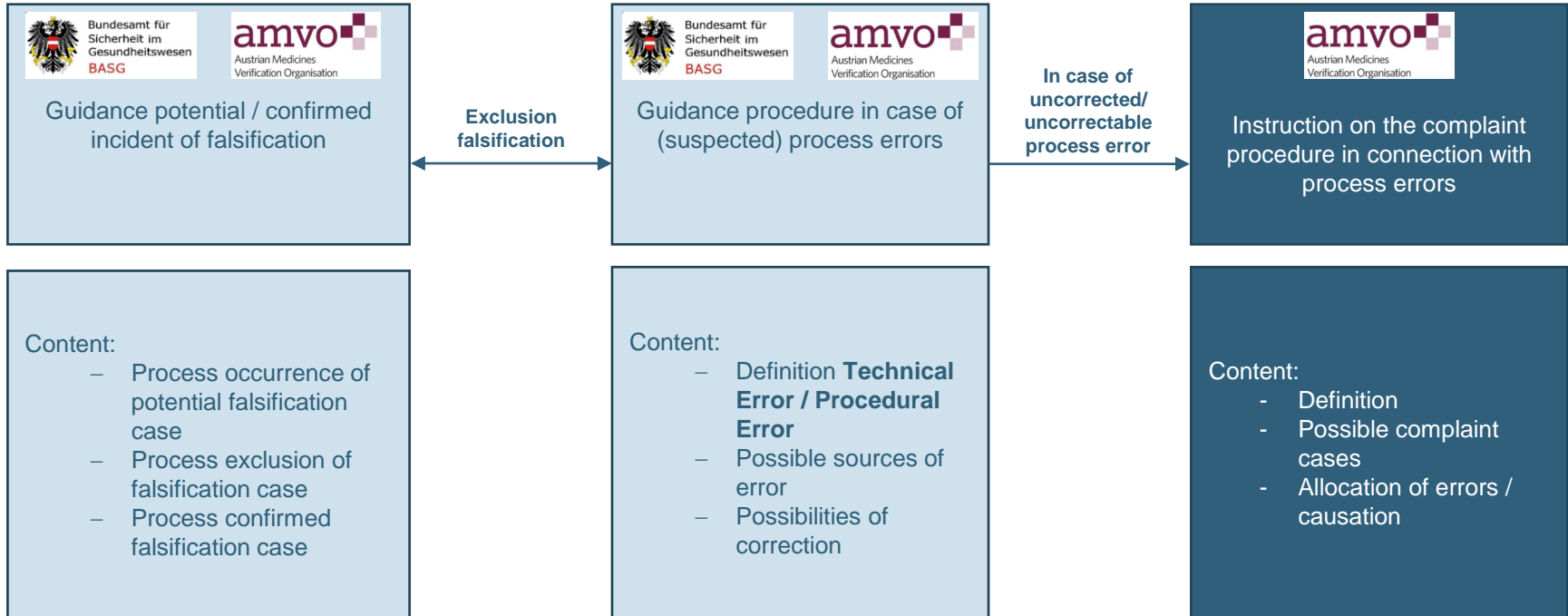
Information regarding the

**Start Phase Operations**  
from 09/02/2020

How to proceed within the context of dispensing or  
verifying medicinal products in Austria during the  
start phase operations

Version 1.0  
01/02/2020

# Processes around Potential Incidents of Falsification after Start Phase



# Process around Potential Incident of Falsification after Start Phase

Documents approved on June 2<sup>nd</sup> 2021

To apply from the end of of start phase operations

Guidance on Potential / Confirmed Incidents of Falsification within the Context of Dispensing or Verifying Medicinal Products in Austria

<https://www.amvs-medicines.at/infothek/leitlinie-potenzieller-bestaetiger-faelschungsfall/>  
<https://www.amvs-medicines.at/en/infothek/guidance-potential-confirmed-incident-of-falsification/>

Guidance Procedure in Case of (Suspected) Process Errors

<https://www.amvs-medicines.at/infothek/leitlinie-prozessfehler/>  
<https://www.amvs-medicines.at/en/infothek/guidance-process-errors/>

Instruction on the Complaint Procedure in Connection with Process Errors

<https://www.amvs-medicines.at/infothek/information-reklamationsprozess/>  
<https://www.amvs-medicines.at/en/infothek/complaints-procedure-instruction/>

# Process around Potential Incident of Falsification after Start Phase

## Duties of industry

- Analysis of all incoming Level 5 alerts by RPC(VPU)/MAH/OBP
- Exclusion of falsification case (confirmation of process error) shall be completed and reported to AMVS within 3 (three) working days
- Correction (if possible) within 10 calendar days.
- AMVS informs BASG and the end user that a process error has occurred
- In case falsification cannot be excluded within 3 working days, BASG will initiate further investigations



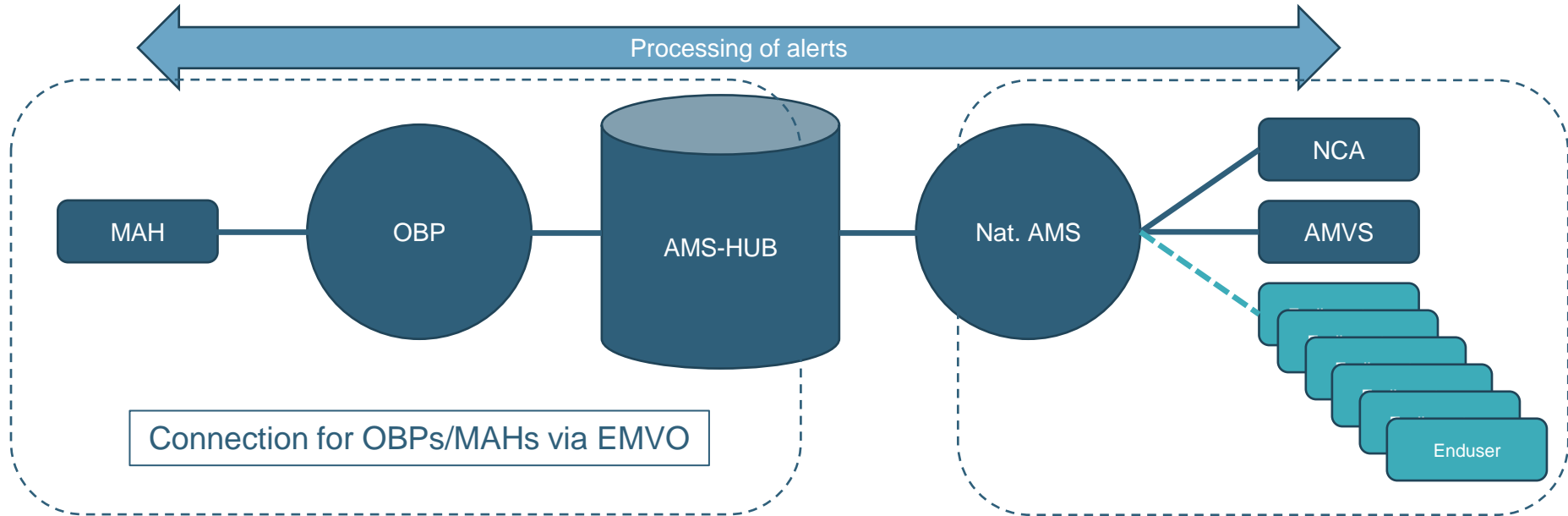
# Process around Potential Incident of Falsification after Start Phase

## Duties of industry



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

# European Alert Management System (EAMS)



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



- Free of charge
- User Management, Assigning alerts and access levels
- View of alert data from all countries participating in the AMS
- Direct processing of alerts via the AMS
- Elimination of email communication with the NMVO
- View of the current status of an alert at any time
- Synchronized communication on alerts of all parties concerned (OBP/MAH, end user, NMVO, NCA)
- View of uploaded information at any time (e.g. photo of the DataMatrix code)
- Thus, equal information status for all concerned parties during the alert processing

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



Develop an  
application using the  
AMS Hub APIs



AMS Portal  
developed by EMVO

- The AMS Portal User Manual - EMVO-01376  
Instructions about how to use the AMS Portal
- EAMS Handbook - EMVO-01392  
Document that links the best practices document with the EAMS
- How to join the EAMS - OBP Guide  
Supports you in joining the EAMS – [link here](#)

# AMVS Digital Alert Management (ADAM)

## - Advantages for NMVO, NCA and Endusers



### **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) **amvs**

## Web Surface for Endusers

Austrian Medicines  
Verification System

AT-9880bf92-1c1c-470b-9d5a-0b767272b1fd

### General Alert Details

Status **new**

Remaining Processing Time **3 days**

Cause Category **Given element is truncated**

### Transaction Information

Alert Timestamp **2023-04-17 6:48 AM**

Target Status **SUPPLIED**

NMVS Error Code **NMVS\_NC\_PC\_02**

NMVS Error Code Description **Unknown serial number.**

### Pack Information

Product Name **5 mg Film-coated tablet**

Given Product Code Scheme **GTIN**

Given Product Code **0908888**

Given Serial Number **4326139975**

Stored Serial Number **43261399750**

Given Batch ID

Given Expiry Date **270930**

### Alert Activities

SYSTEM - 2023-04-17 6:49 AM → **new**

### Comment List

select a comment

+ attachments

add comment

### Attachments (0)



[Choose files](#) or drop them here.

Mobile Upload

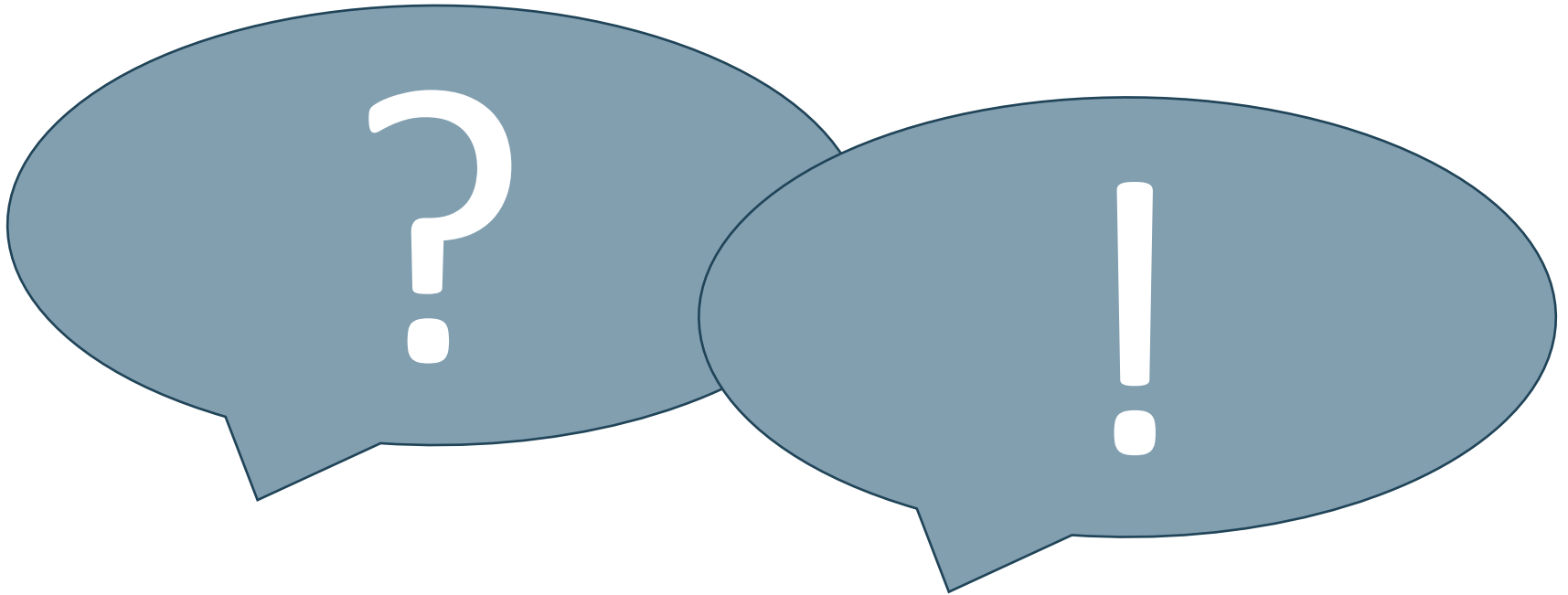
# European Alert Management System (EAMS) and AMVS Digital Alert Management



## Final Conclusions and Next Steps

- AMVS and BASG encourage all MAHs and OBPs to participate in the EAMS
- Software Suppliers of Endusers are informed on the implementation and encouraged to implement the Web solution (GUI)
- Friendly User Tests with Endusers of all groups are envisaged for summer/autumn 2023

# Questions and Discussions





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](mailto:office@amvs-medicines.at) or +43 1 9969499 0

# DISCLAIMER

The material in this presentation has been prepared by AMVS GmbH and is general background information about the FMD project report current as at the date of this presentation. This information is given in summary form and does not purport to be complete.

Any content of this presentation may not be used without prior written permission from AMVS GmbH.

© AMVS – Austrian Medicines Verification System GmbH

Management: Christoph Lendl, MSc.

Square One, Leopold-Ungar-Platz 2, Stiege 1, Top 134, 1190 Vienna, Austria

+43 1 9969499-0

office@amvs-medicines.at; amvs-medicines.at

FN 466094 h; HG Wien; UID: ATU 72357059; DVR Nr.: 4018122