Information Event Pharmaceutical Companies

Livestream Event

14.06.2022

amvs

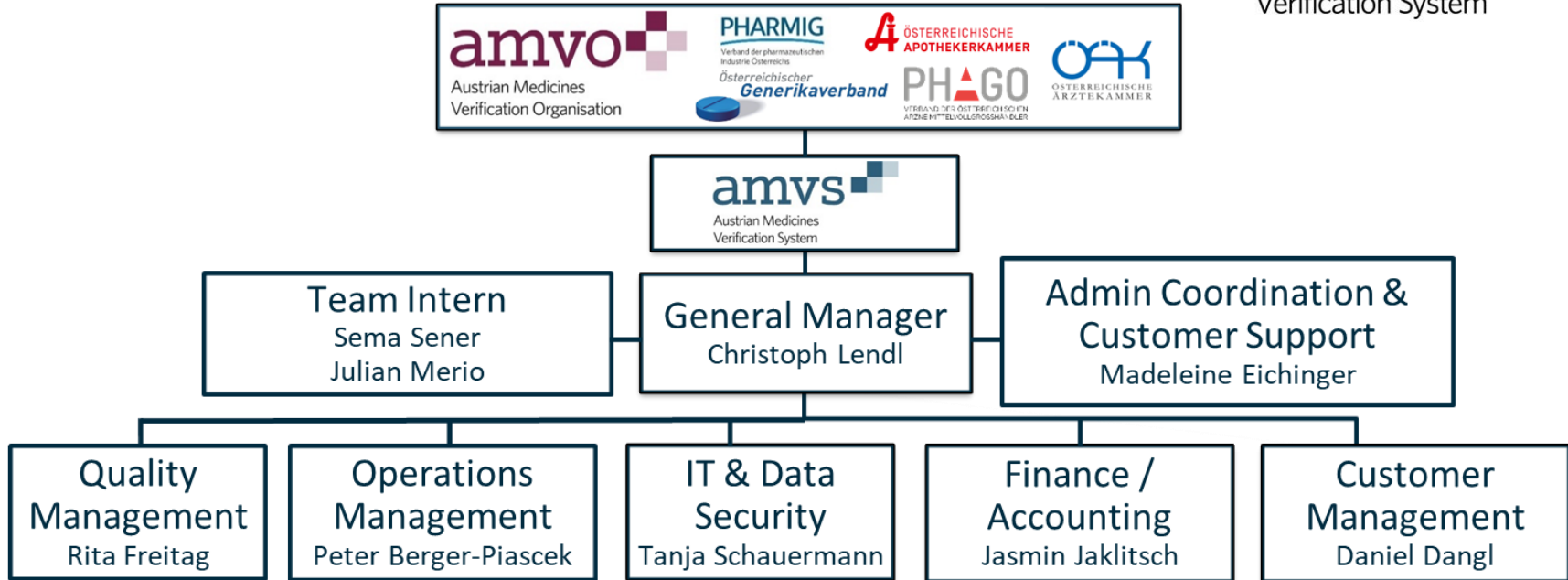Austrian Medicines
Verification System

Agenda

- AMVS Organisation
- Status of Contractual Relations and Fee Model
- Summary Codierung
- Alert Statistics
- New Features in the System
- European Alert Management System
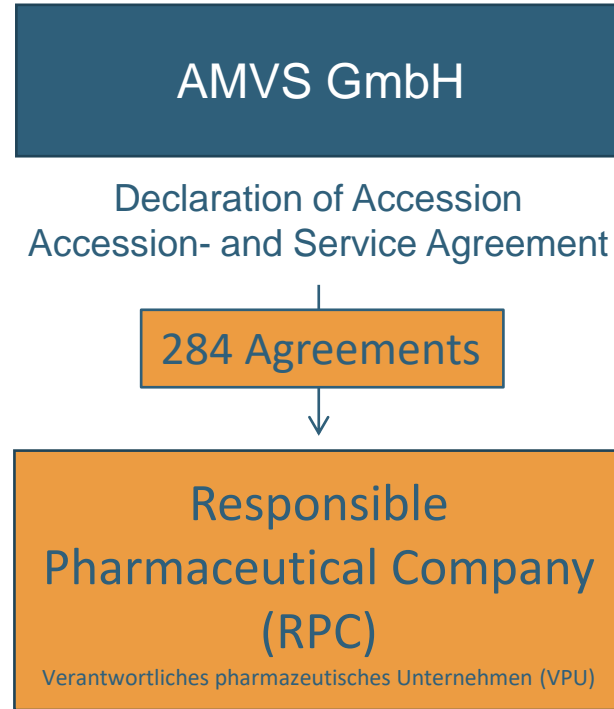- Transition from Start Phase to Operational Phase

AMVS Organisation

Conctractual Relations –
Responsible Pharmaceutical Companies

AMVS GmbH

Declaration of Accession
Accession- and Service Agreement

284 Agreements

Responsible
Pharmaceutical Company
(RPC)
Verantwortliches pharmazeutisches Unternehmen (VPU)

Status: 03.05.2022

Operational Fee

Fixed Turnover based Part

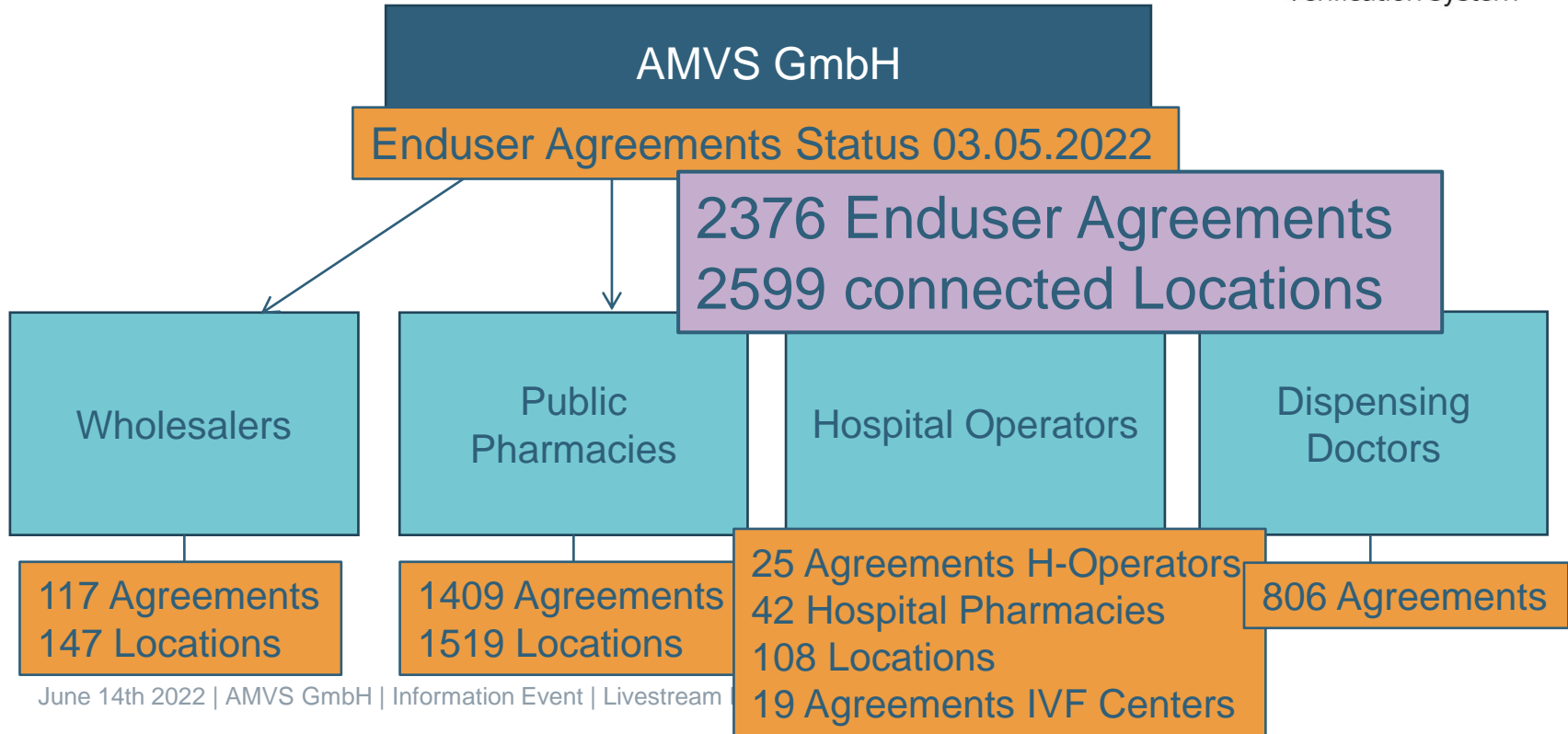| Turnover € / User p.a.	Fee € / User p.a.
< 100k	400
100k-1.5 Mio	1 200
1.5-3 Mio	2 400
3-10 Mio	4 000
10-20 Mio	6 000
20-30 Mio	12 000
30-50 Mio	20 000
50-70 Mio	28 000
70-100 Mio	36 000
100-150 Mio	44 000
150-200 Mio	52 000
200-250 Mio	60 000
< 250 Mio	68 000

Operational Fee

amvs
Austrian Medicines
Verification System

Variable Volume-based Part

Price-Quantity Scale p.a.	€/serial number
≤ 2.000.000	0,007
≥ 2.000.001	0,004

Number of uploaded serial numbers based on AMVSystem

Contractual Relations – Endusers

AMVS GmbH

Enduser Agreements Status 03.05.2022

2376 Enduser Agreements
2599 connected Locations

Wholesalers

Public Pharmacies

Hospital Operators

Dispensing Doctors

117 Agreements
147 Locations

1409 Agreements
1519 Locations

25 Agreements H-Operators
42 Hospital Pharmacies
108 Locations
19 Agreements IVF Centers

806 Agreements

Summary Coding

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

Summary Coding

- Starting from February 9th 2019 the printing of the EAN-13 1D-Barcode is not required anymore. Recommendation to <u>no longer place</u> on packs <u>or remove</u> in the course of planned changes to the packaging

- Upload of the <u>Austrian „Pharmazentralnummer"</u> (PZN – 7digits incl. Check digit) using the EMVS Master Data Elements via the European Hub and stored in the national repository system <u>as a „national code".</u>

- <u>Character Set for Serial Numbers und Batch-ID</u>: No usage of Y and Z, special characters and small letters (see also Q&As of EU Commission, Question 2.23.)

Summary Coding

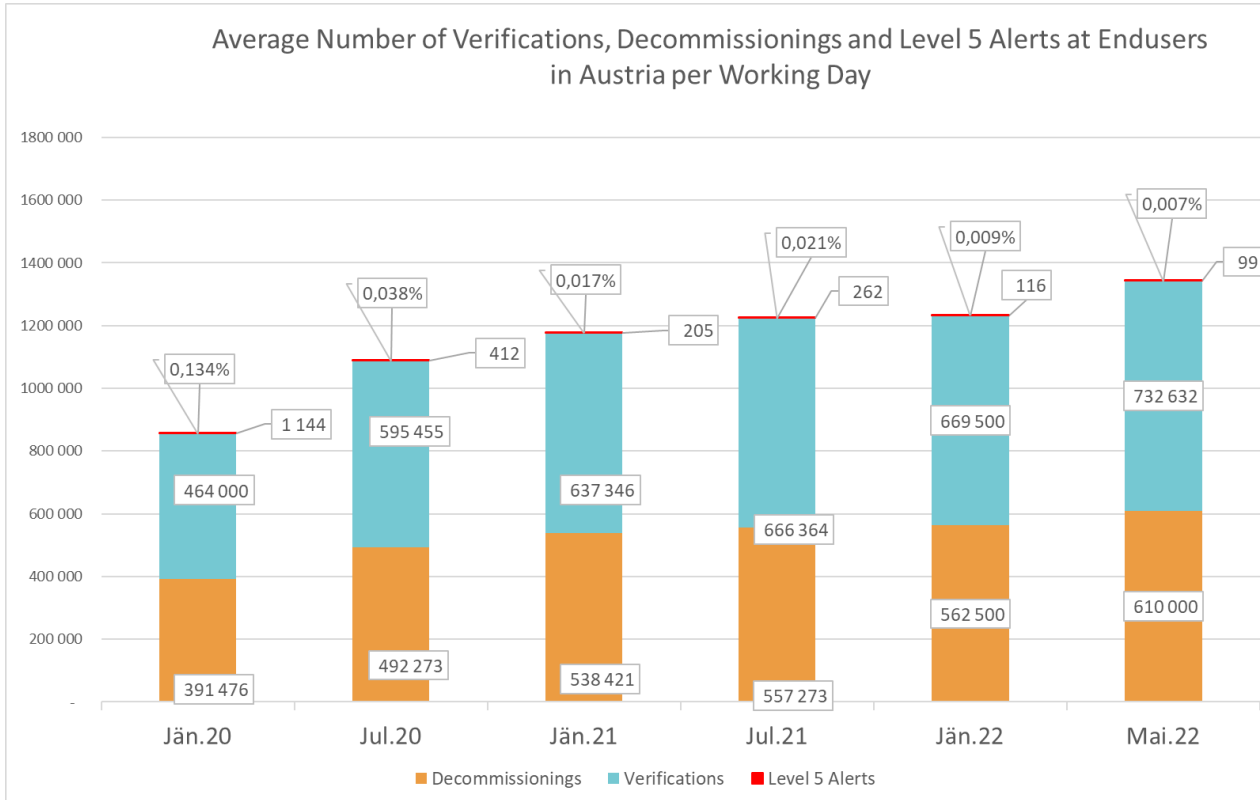## Outlook: New provisions for expiry date format

- 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
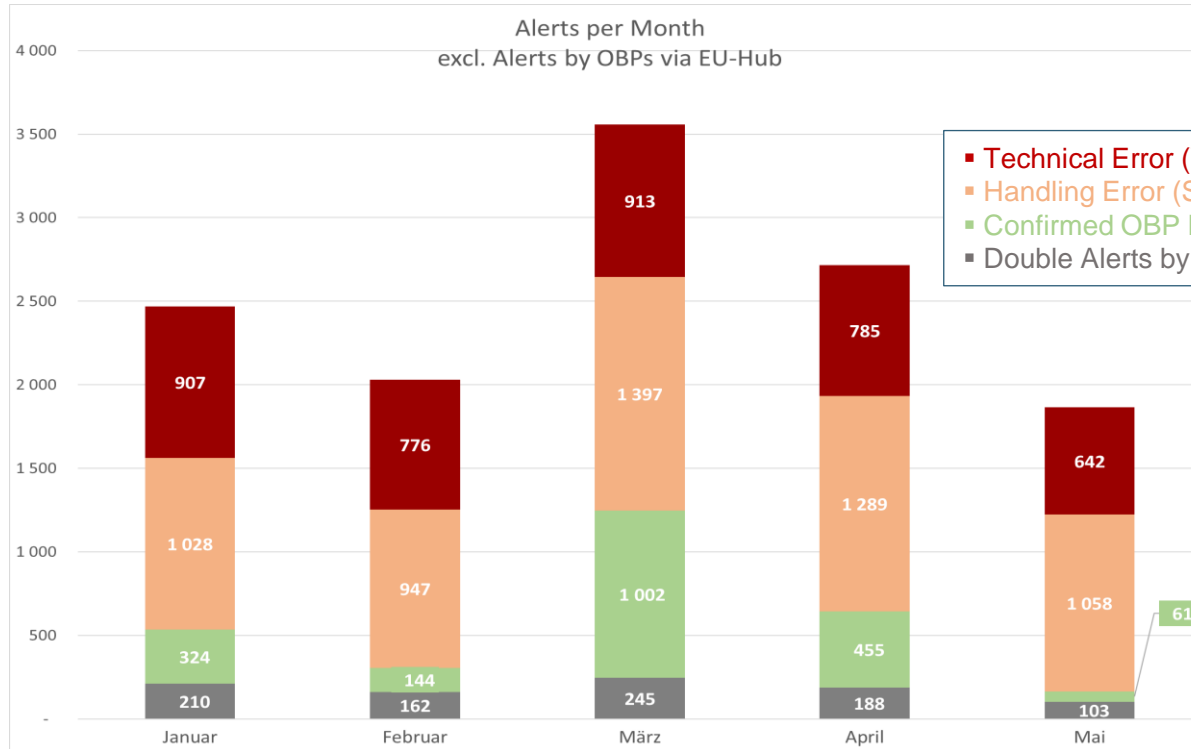
Summary Coding

Upload of Multi Market Packs

- In <u>each national system</u> of a country where the product is placed on the market

- Applies to each batch of the product

- Inter-market queries are <u>not sufficient</u>

- Multi market packss not uploaded in each affected national system cause problems for end users (alert ID with different country ID, different behavior when "double dispensing")

Enduser Transactions and Alerts

Average Number of Verifications, Decommissionings and Level 5 Alerts at Endusers in Austria per Working Day

Enduser Transactions and Alerts

Alerts per Month
excl. Alerts by OBPs via EU-Hub

- Technical Error (Wrong Data Submission)
- Handling Error (Status Change not possible)
- Confirmed OBP Error
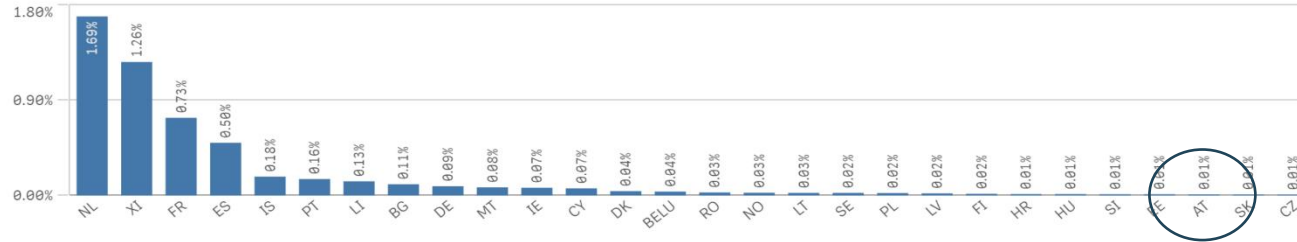- Double Alerts by Verify / Dispense

OBP Errors March:

37 % MAH Transfer (298 alerts)
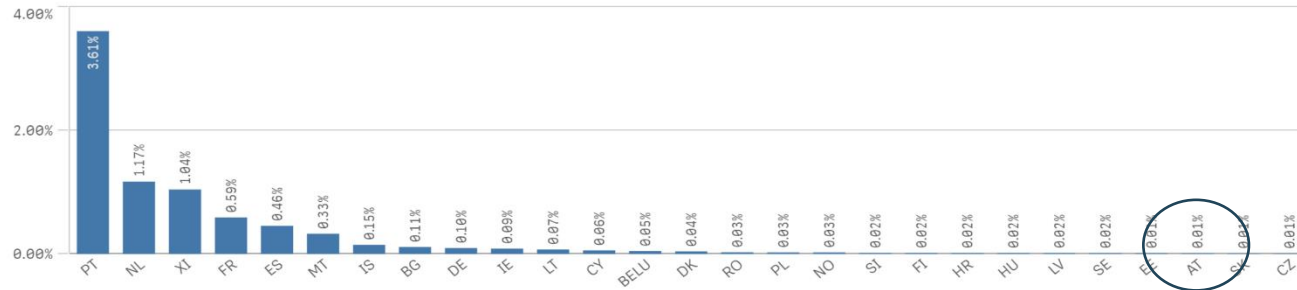51 % QA release of 2 batches without checking upload (501 alerts)

OBP Errors April

80% delivery of a batch with incorrect expiry date; correction after 24 hours

Weekly Alert Rates Compared across Europe

Alert Rate incl. OBP-Alerts

Release 1.10 AMVSystem

Changes / New Features

- Changes – Double Decommission by the same enduser
- New version of the interface V5 to the AMVSystem
  - Display of the product name at verifications/decommissions
  - At Verifications → Information if an UNDO is possible

Rollout productive system Austria: 16th May

Rollout productive system Germany: 7th June

Release 1.10 AMVSystem
Changes – Double Decommission by the same enduser

Decommission		
Dispense, Fee Sample, Destroy, Recall,…		
	Alert	Time Frame
national transactions	after 5th attempt	after 1 year
From other national system incoming transactions	after 5th attempt	after 1 year

Example:
Pack was already decommissioned twice, another decommission within 1 year creates a **warning**
Pack was already decommissioned one time, another decommission after 1 year creates an **alert**
Pack was already decommissioned four times, another decommission creates an **alert**

Important: From June 7th German system accepts **one** double Decomission **within 15 minutes** (currently each double decommission creats an alert).

Release 1.10 AMVSystem
New version of the interface V5 to the AMVSystem

Display of the product name at verifications / decommissions

When a national pack(*) is verified/decommissioned, the product name stored in the AMV system is returned to the V5 interface and can thus be displayed to the **enduser** for verification.

Increasing security

* In one of the next versions of the AMVSystem, the product name of a non-national pack will also be made available at the interface to the AMVSystem as a further step to increase security.

Release 1.10 AMVSystem
New version of the interface V5 to the AMVSystem

At Verifications → Information if an UNDO is possible

In case of a verification, the AMVSystem returns to the **enduser** at the V5 interface whether the decommission was performed by the same enduser and whether the decommission can still be reversed (10 days).
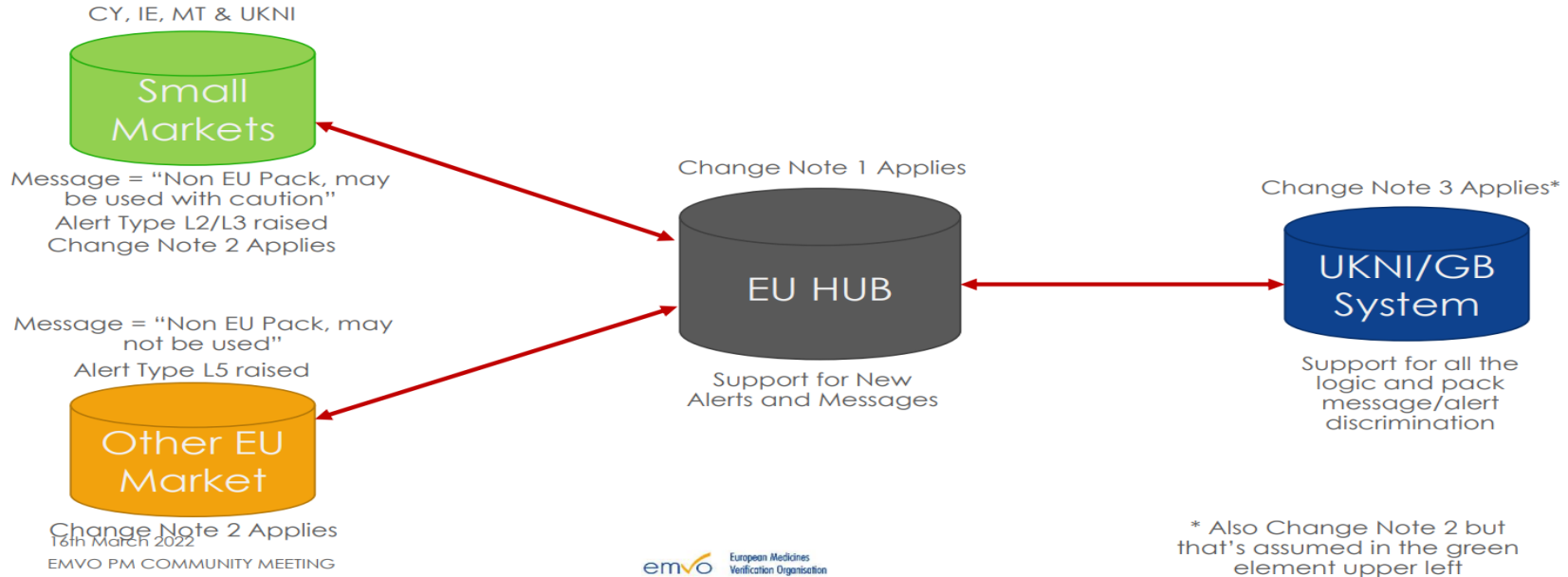
Avoidance of alarms

BREXIT CHANGES for EMVS

- Ammendment of DR leads to differentiation between markets when handling GB packs brought to market after date of Brexit (Jan 1, 2021)
  - IE/CY/MT/NI (Northern Ireland): GB packs trigger warning message L2/3
  - Other: GB pack triggers alert message L5

BREXIT CHANGES for EMVS

CHANGES FOR THE DR

CY, IE, MT & UKNI

Small Markets

Message = "Non EU Pack, may be used with caution"
Alert Type L2/L3 raised
Change Note 2 Applies

Message = "Non EU Pack, may not be used"
Alert Type L5 raised

Other EU Market

Change Note 2 Applies

Change Note 1 Applies

EU HUB

Support for New Alerts and Messages

Change Note 3 Applies*

UKNI/GB System

Support for all the logic and pack message/alert discrimination

* Also Change Note 2 but that's assumed in the green element upper left

16th March 2022
EMVO PM COMMUNITY MEETING

emvo European Medicines Verification Organisation

BREXIT CHANGES for EMVS

amvs
Austrian Medicines
Verification System

IMPLEMENTATION PLAN

Hub
o In V1.12 so by December this year.

NMVS
o General changes by Spring 2023 latest

NMVS GB
o TBC noting that Autumn for the unique changes is workable but Spring for the general changes is needed to allow end user change and testing.

16th March 2022
EMVO PM COMMUNITY MEETING

emvo European Medicines
Verification Organisation

Implementation European Alert Management System (EAMS)

- EAMS will facilitate communication when handling alerts
- Pilot project on EU AMS-Hub by industry already underway
- Roll out of Austrian AMS planned for Q4 2022
- Use initially for industry, BASG and AMVS

Implementation European Alert Management System (EAMS)
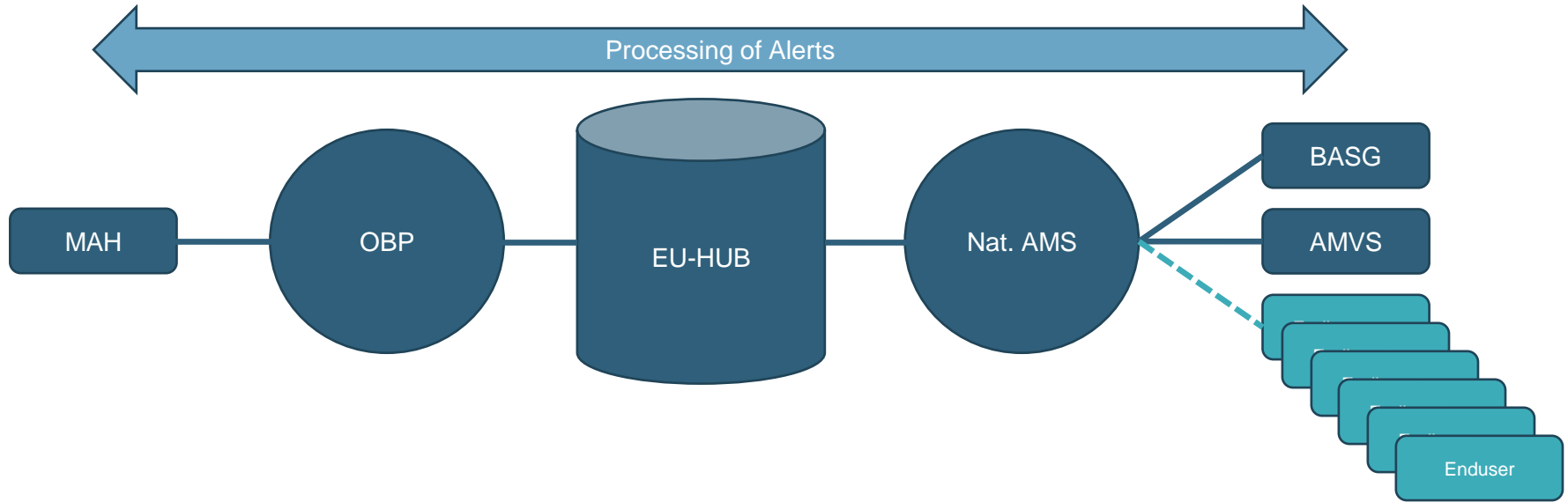
Start Phase Operations from 09.02.2020

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

Bundesamt für Sicherheit im Gesundheitswesen
BASG

amvo
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

Guidance potential / confirmed incident of falsification

Exclusion falsification

Guidance procedure in case of (suspected) process errors

In case of uncorrected/ uncorrectable process error

Instruction on the complaint procedure in connection with process errors

Content:
– Process occurrence of potential falsification case
– Process exclusion of falsification case
– Process confirmed falsification case

Content:
– Definition **Technical Error / Procedural Error**
– Possible sources of error
– Possibilities of correction

Content:
- Definition
- Possible complaint cases
- Allocation of errors / causation

Process around Potential Incident of Falsification after Start Phase

Documents approved on June 2nd 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

Alert

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

Day 0

Correction of process errors
if possible
within 10 calendar days

Day 0

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

Current Challenges Industry

- Non uploaded serial numbers – Error „Serial Number not found"
  - → Monitoring of <u>all alerts</u> and feedback to AMVS by industry
  - → After the start phase operations: pack will not be dispensed, correction of the error within 10 calendar days or complaint
- Batch Release and delivery to endusers before upload – „Batch not found" error
  - → Currently, approx. 3-4 batches/month which have yet to be uploaded are being delivered to endusers
  - → Further adaptation of quality systems which prevents delivery before uploading recommended
  - → After the start phase operations: packs will not be dispensed until batch is uploaded
- Alert Management by OBP, MAH and VPU
  - → OBP receives all Alert-Data via his EU-Hub Interface
  - → <u>All alerts</u> generated by Austrian end users must be analysed and reported back
  - → Coordination of responsibilities between OBP, MAH and RPC (VPU) especially when RPC (VPU) and MAH/OBP do not belong to the same group of companies

Transition from Start Phase to Operational Phase

Alert Profil for one Working Day in May
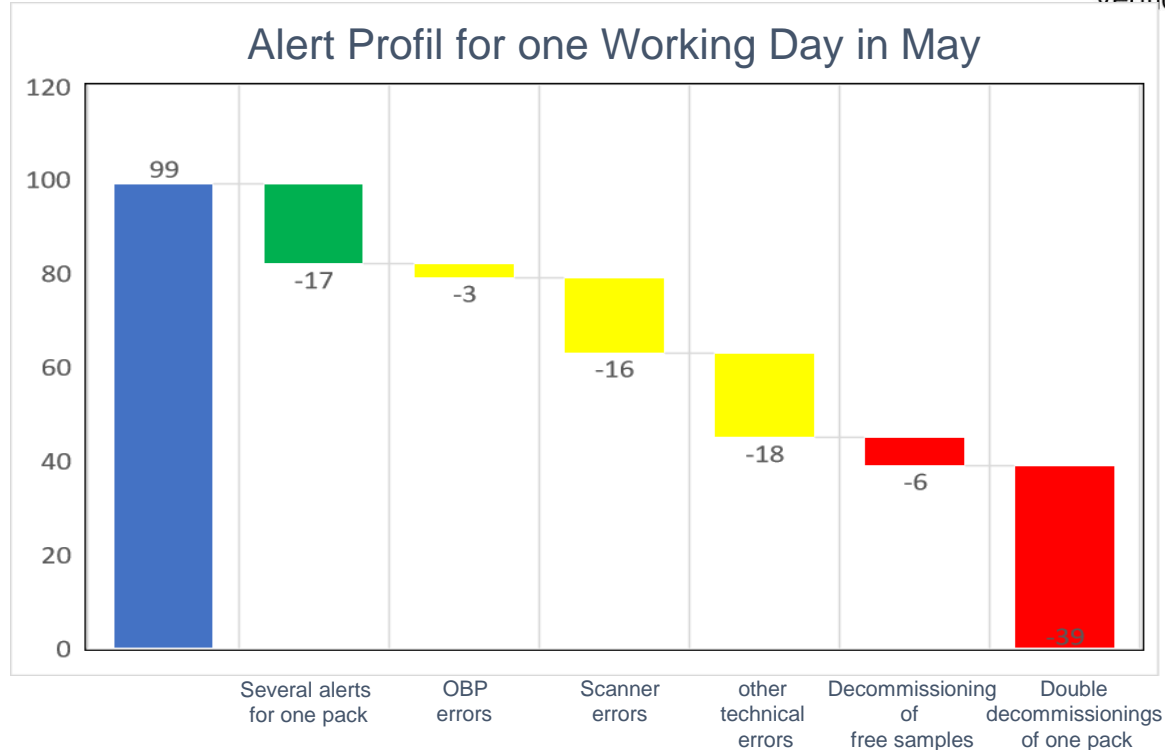
Transition from Start Phase to Operational Phase

Service for endusers:

Explanatory Video and Service Leaflet incl. Check-List

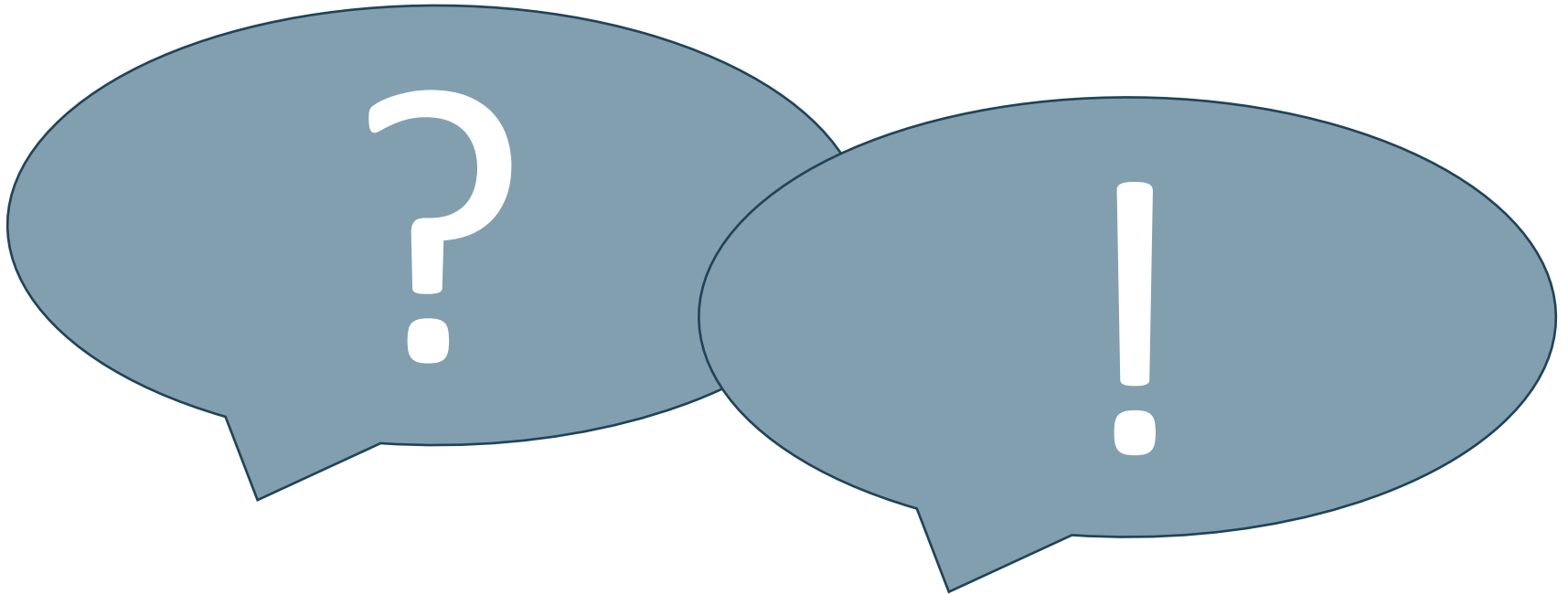# Questions and Discussion

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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