Information Event Pharmaceutical Companies

amvs
Austrian Medicines Verification System

Livestream Event

14.11.2025

Agenda

Austrian Medicines Verification System

- AMVS Organisation, Status Agreements und Fee Model New from 2026
- Coding and Data Quality
- End of Startphase Operations by 09.02.2026
  - Alert Statistics
  - Tasks of the Pharmaceutical Companies
  - Alert Management System and National Guidance on the Investigation of potential falsifications
- Current topics at EU Level
  - Data Deletion and Oracle Sovereign Cloud

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AMVS Organisation

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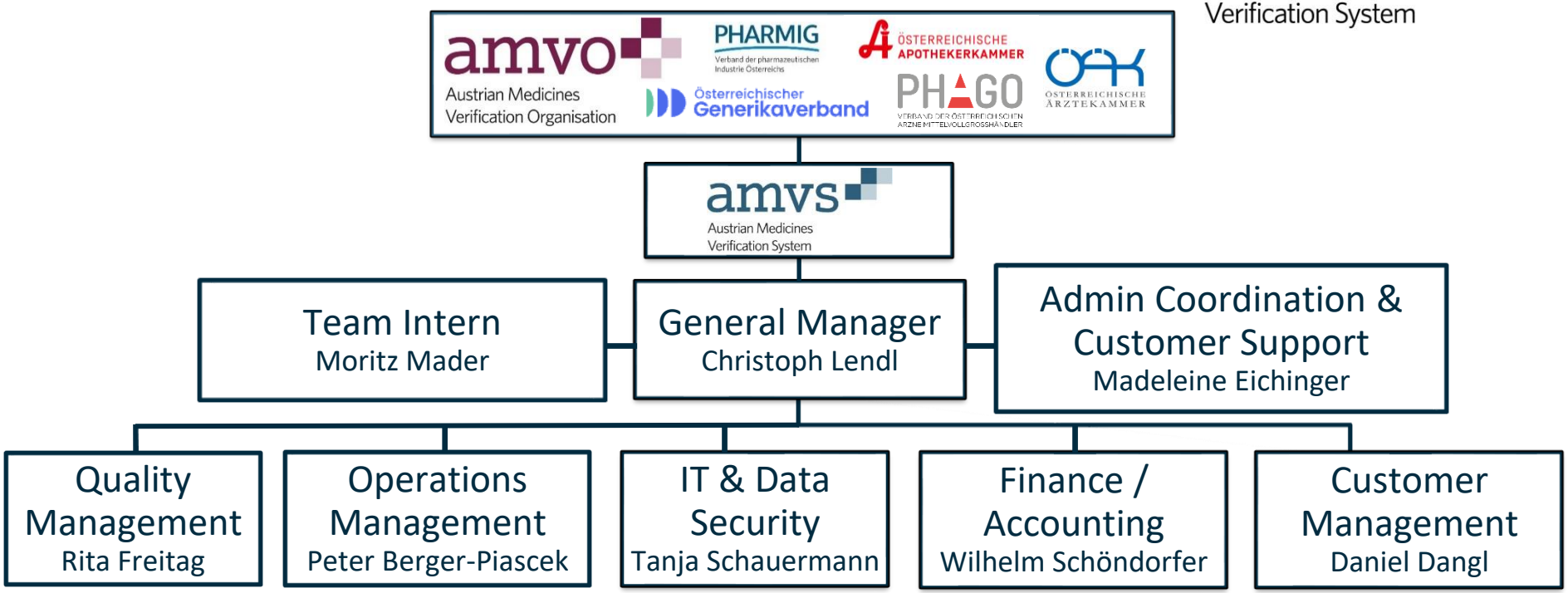

Contractual Relations – Responsible Pharmaceutical Companies

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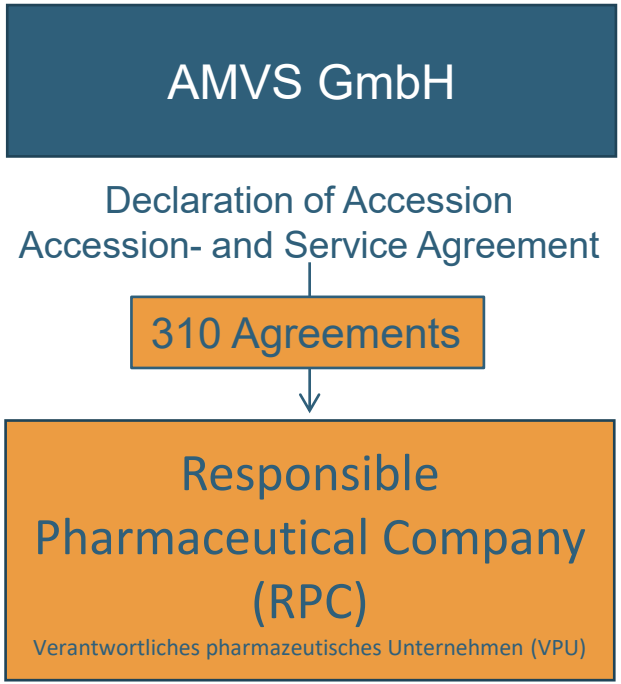

Status: 31.10.2025

Operational Fees
New Fee Model from 2026

Austrian Medicines Verification System

Fixed Turnover-based Part

- Reduction of the fee by 5% for all user groups

Variable Volume-based Part

- Reduction of the fee by 0.001€ per serial number for both fee classes

Invoicing

- Reduction of number of invoices per year

Turnover Declaration and Confirmation of Agreement Changes

- Mailing until end of November

Operational Fees
New Fee Model from 2026

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Fixed Turnover-based Part

Turnover € / User p.a.	Fee 2024-2025 € / User p.a.	Fee NEW from 2026 € / User p.a.
User group < 100k	360	342
User group 100k-1.5 Mio	1 080	1 026
User group 1.5-3 Mio	2 160	2 052
User group 3-10 Mio	3 600	3 420
User group 10-20 Mio	5 400	5 130
User group 20-30 Mio	10 800	10 260
User group 30-50 Mio	18 000	17 100
User group 50-70 Mio	25 200	23 940
User group 70-100 Mio	32 400	30 780
User group 100-150 Mio	39 600	37 620
User group 150-200 Mio	46 800	44 460
User group 200-250 Mio	54 000	51 300
User group > 250 Mio	61 200	58 140

Operational Fees
New Fee Model from 2026

Austrian Medicines Verification System

Variable Volume-based Part

Price-Quantity Scale p.a.	€/serial number 2024-2025	€/serial number NEW from 2026
≤ 2 000 000	0.007	0.006
≥ 2 000 001	0.003	0.002

Based on the number of uploaded serial numbers into the AMVSystem

Operational Fees
New Fee Model from 2026

Austrian Medicines Verification System

Invoicing from 2026:
2 invoices / year

<u>Fixed Turnover-based Part:</u>
Turnover Declaration until 31st January — Invoicing until 28th February

<u>Variable Volume-based Part:</u>
Uploads January – December — Invoicing until 31st January of the following year

Payment Deadline 30 Days

Contractual Relations – Endusers

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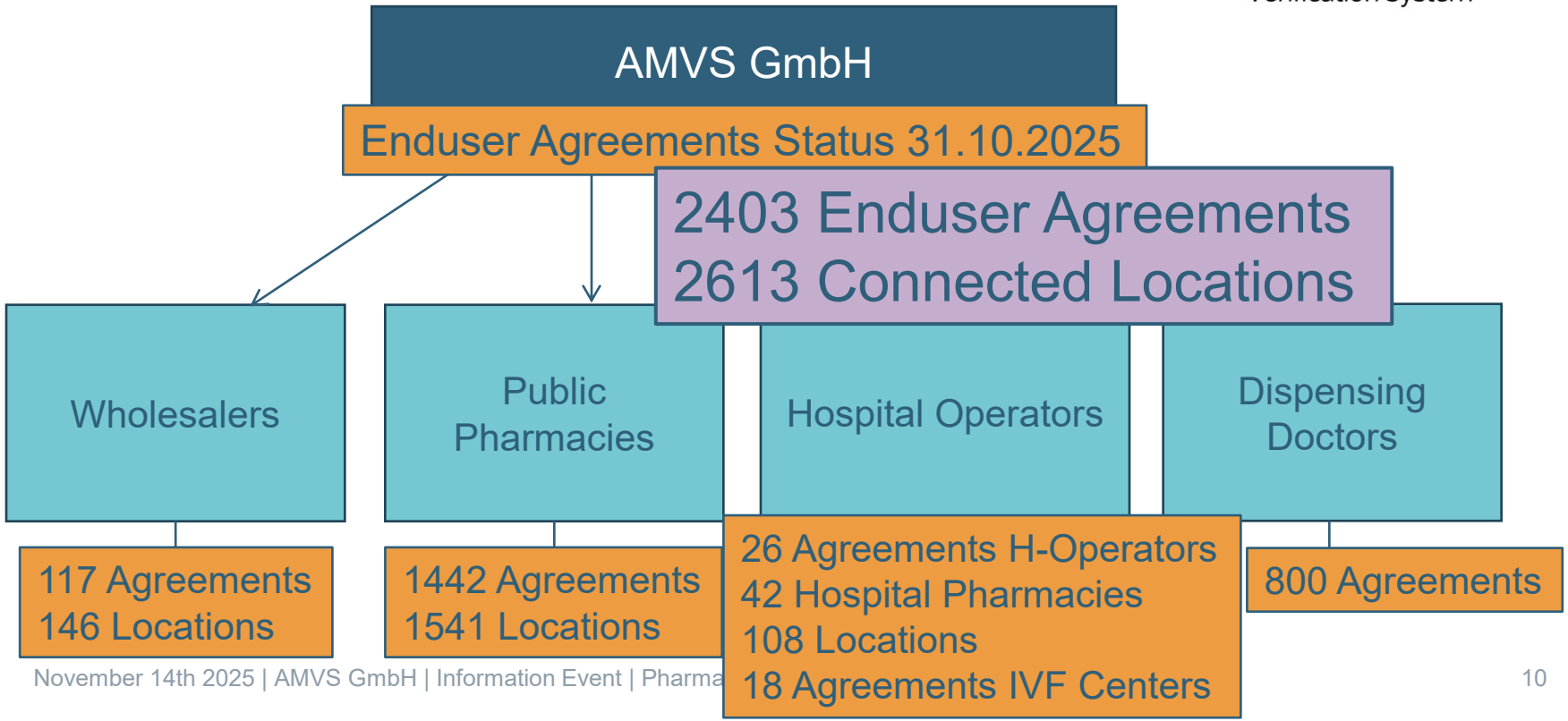

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Coding and Data Quality

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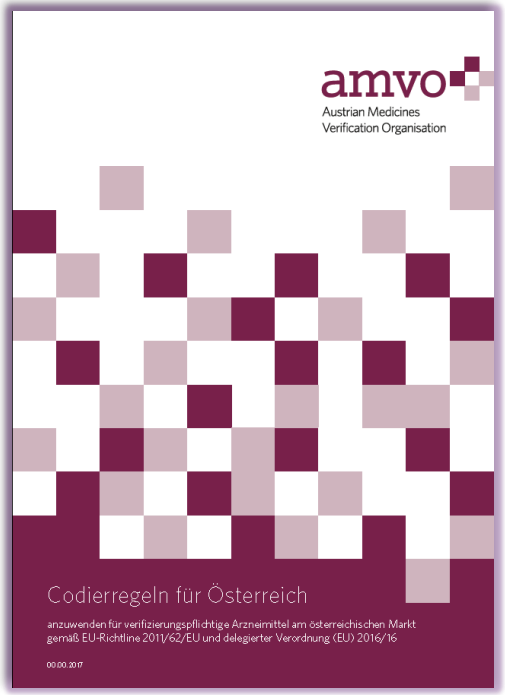


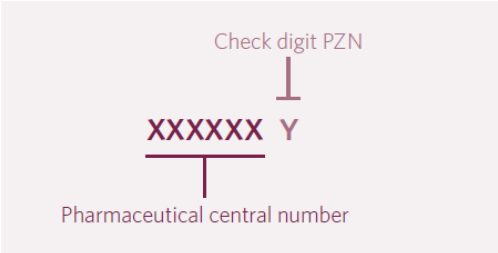
Coding Rules for Austria
Version 4.0 published in November 2020

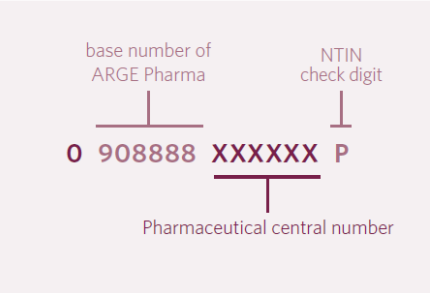
German Version:
https://www.amvs-medicines.at/media/1693/amvo_codierregeln_v4.pdf
English Version:
https://www.amvs-medicines.at/media/1694/amvo_coding-rules_v4_en.pdf

Coding and Data Quality

Austrian Medicines Verification System

General: Productcode is the Austrian NTIN (NTIN-AT) generated from the Austrian PZN (PZN-AT – 7 digits incl. check digit)





Attention: Check digit of PZN most likely different to check digit of NTIN

Coding and Data Quality

Austrian Medicines Verification System

Multi Market Packs need a common product code

- GTIN as produkt code or
- NTIN of another country under certain conditions possible (no further country specific elements within the DataMatrix code)
- For Austria no 5th element in DataMatrix code required and not possible (no identifier defined)

Coding and Data Quality

Shared Packs with Germany

2 options possible that were agreed between AMVO/AMVS and SecurPharm/ACS Pharmaprotect

Option 1:
Productcode GTIN
Elements in the
GS1 DataMatrix: 5

PC: 09099999000970
SN: A1B2C3D4E5
Lot.: ABC123
EXP: 12 2022
NHRN: 12345678

Option 2:
Productcode NTIN-DE
Elements in the
GS1 DataMatrix: 4

PC: 04150123456782
SN: A1B2C3D4E5
Lot.: ABC123
EXP: 12 2022

Disclaimer: Information on coding in Germany is non-binding and does not replace consultation with SecurPharm / ACS Pharmaprotect.

Coding and Data Quality

Austrian Medicines Verification System

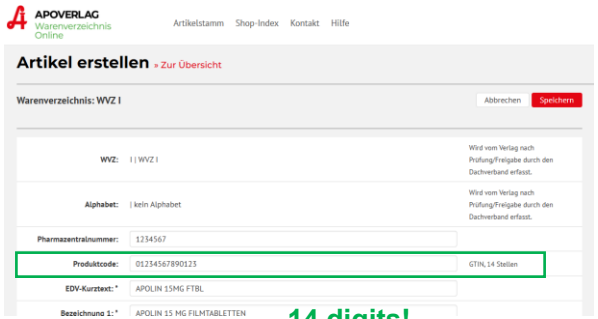
Regardless of the coding variant selected for multi-market packs, the PZN-AT is not part of the DataMatrix code.

⇒ Enduser needs to know, which PZN is assigned to a certain product code!

- Upload of the PZN-AT as national code (NHRN) in the Austrian market specific EMVO Master data

  AND

- Storing of the product code in Warenverzeichnis of APOVerlag



14 digits!
only numbers 0-9

Coding and Data Quality

Austrian Medicines Verification System

The 1D linear barcode is not needed any more for single market packs as well as for multi market packs

We recommend to

- Not print any 1D linear barcode for new products
- Remove the 1D linear barcode within the next package version

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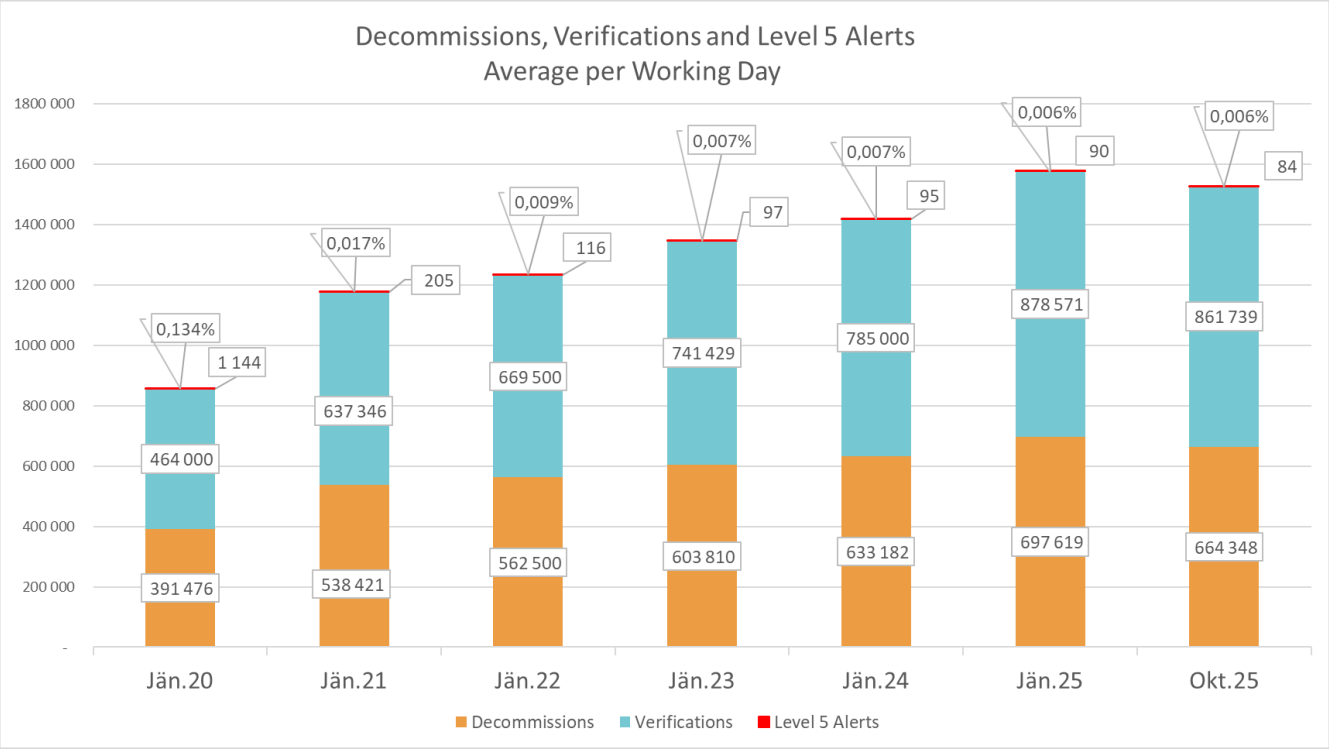
Alert Statistics – General Overview

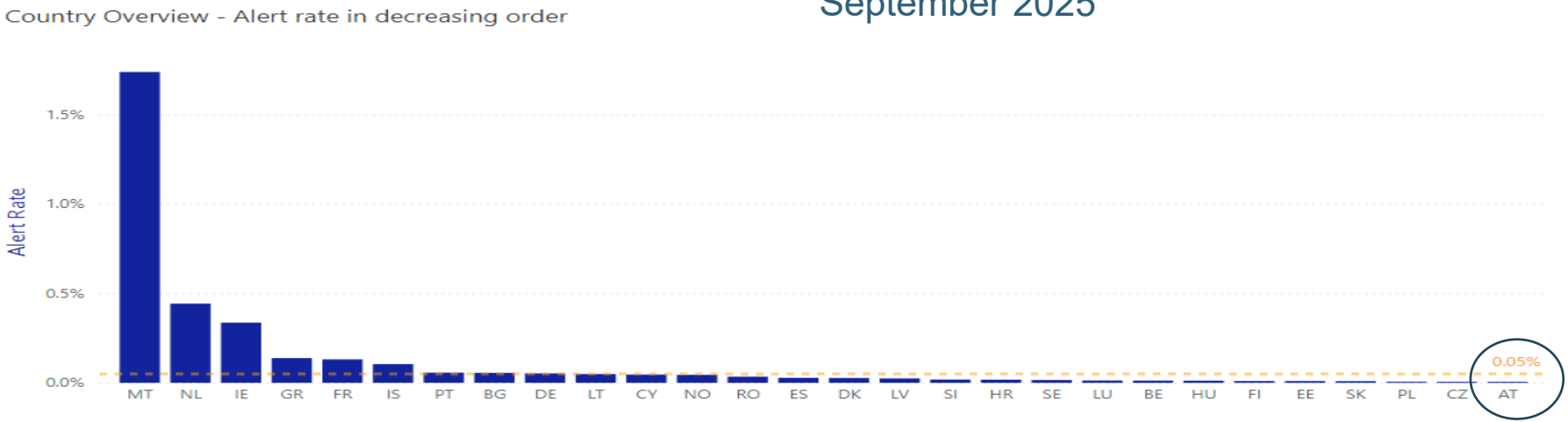
Austrian Medicines Verification System



Alert Statistics – Alert Rates in Europe

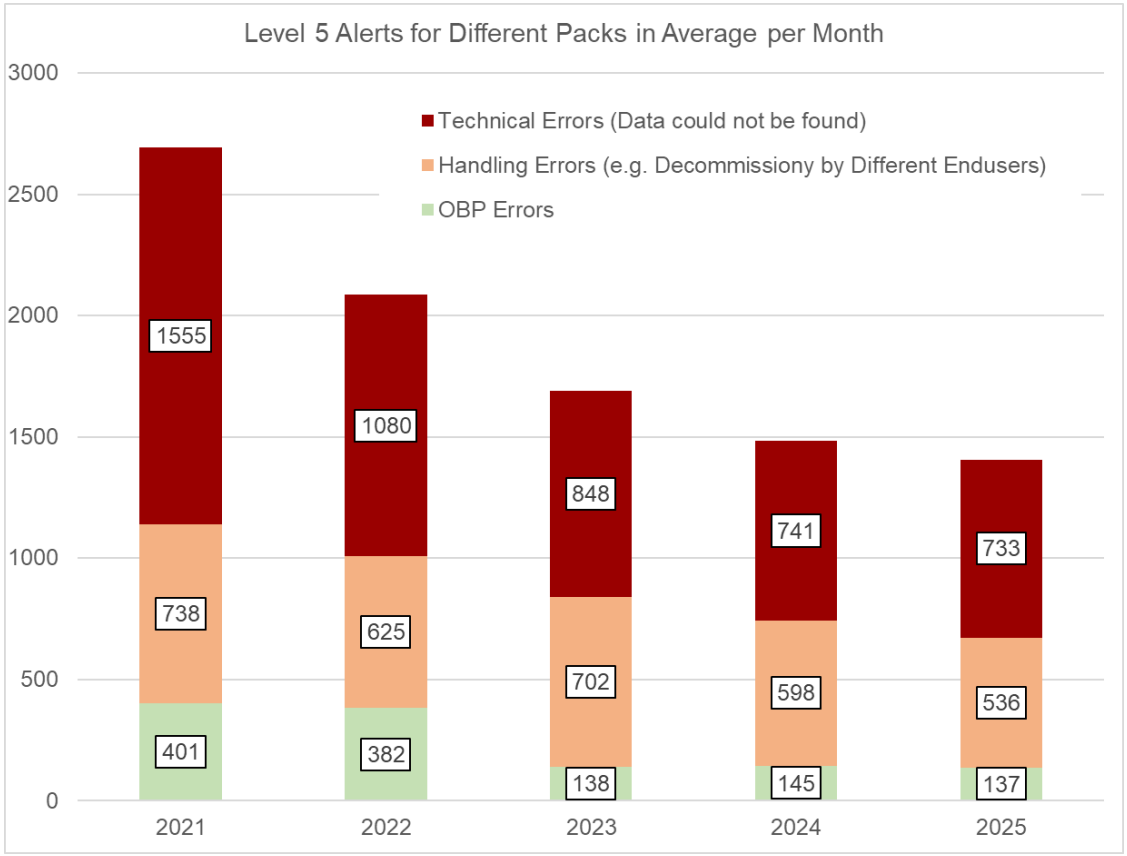
Austrian Medicines Verification System

September 2025



Alarmrate inkl. OBP-Alerts

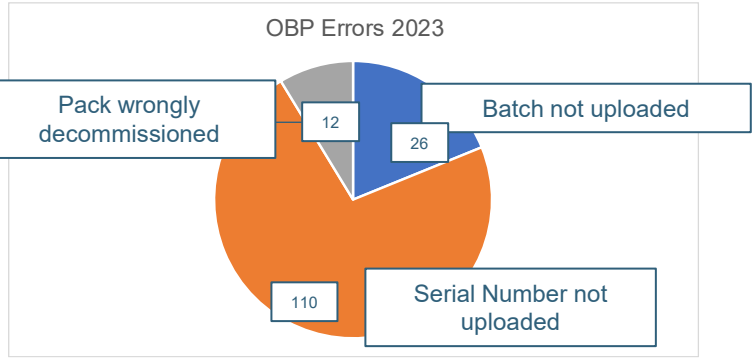
Alert Statistics – Alerts per Category

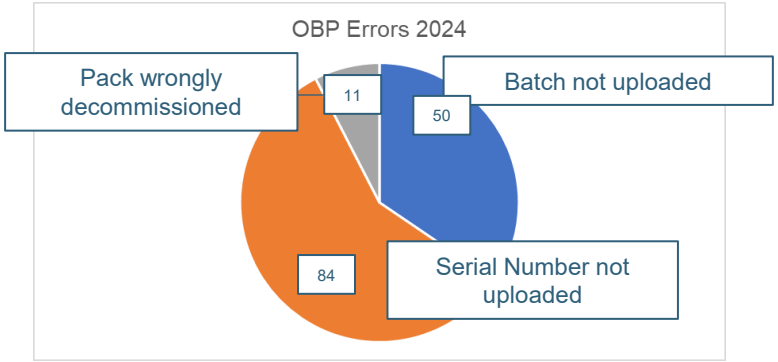


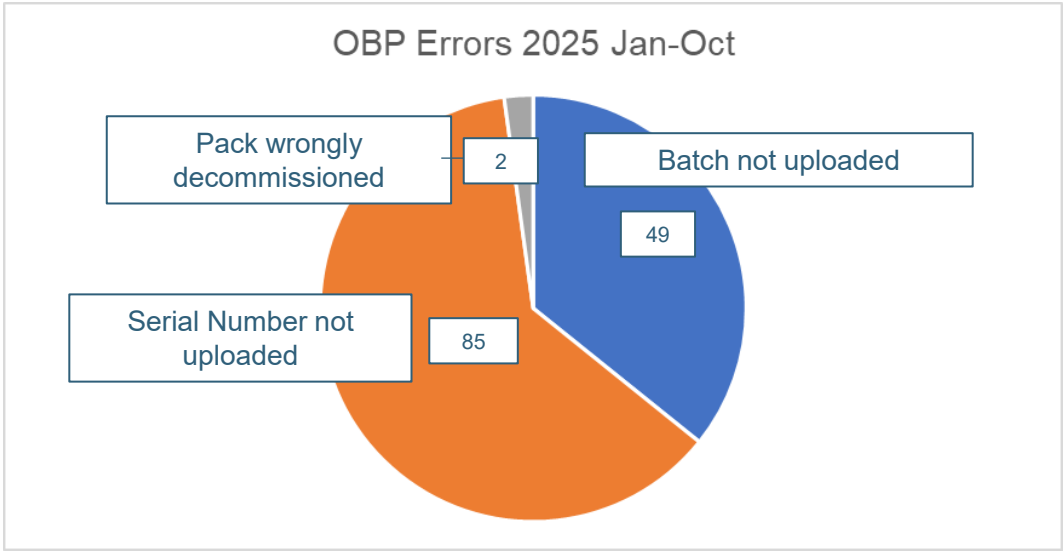
Austrian Medicines Verification System

Alert Statistics – OBP Errors

Average Number of Packs per Month







OBP Errors

Austrian Medicines Verification System

Batch not uploaded - still delivered

- 21 Batches from 16 companies so far affected in 2025
- Number of alerts per incident from 3 bis 169

→Coordination with QP required (Coordination Batch Release with Batch Upload)

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

OBP Errors

Austrian Medicines Verification System

Serial number not uploaded - batch partially uploaded

- „Blind Passenger“ packs
- 237 batches from 68 companies affected so far in 2025
- Number of affected serial numbers per batch from 1 to 107
- 3 companies reload affected serial numbers

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 engagement enhanced

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

Timeline to Operational Phase

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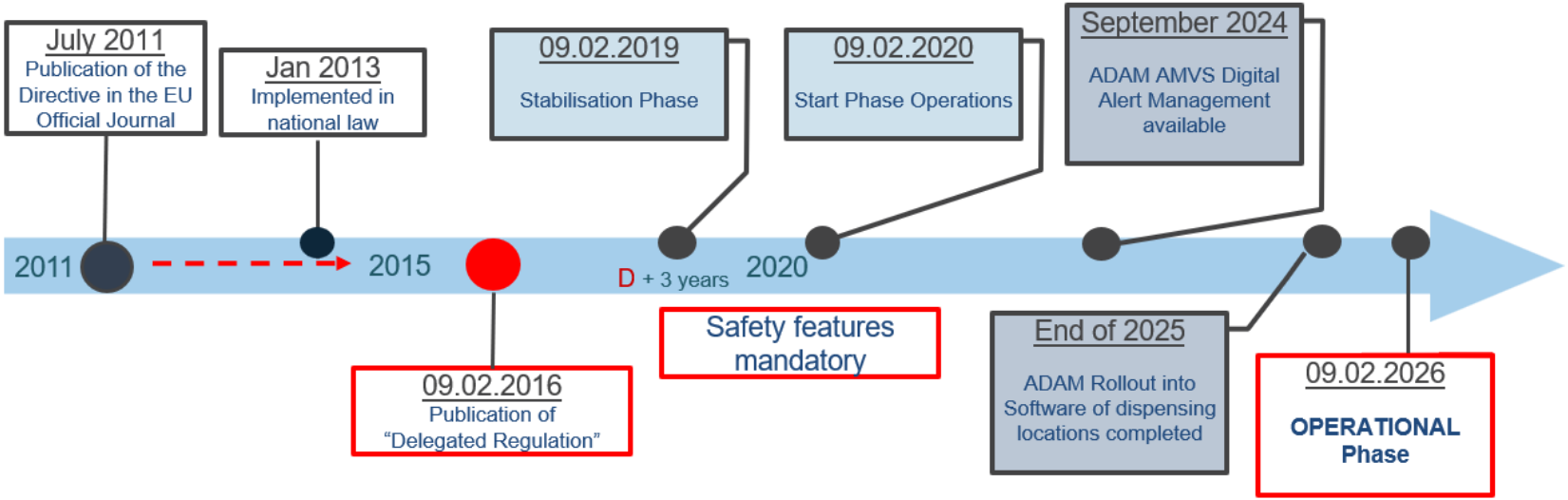


Operational phase from 09.02.2026

Austrian Medicines Verification System

Level 5 alerts are classified as potential falsification incidents

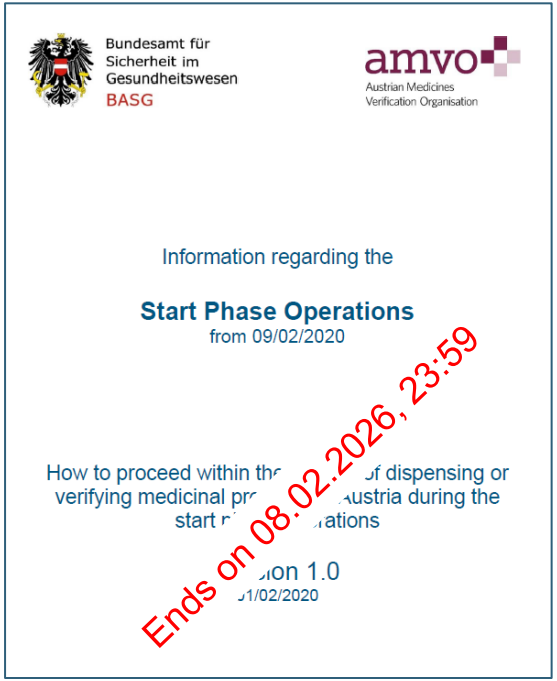
Pack remains at the enduser‘s premises

The alert must be investigated within 3 working days.

- reasonable grounds to suspect an incident of falsification if alert can not be solved within 3 working days

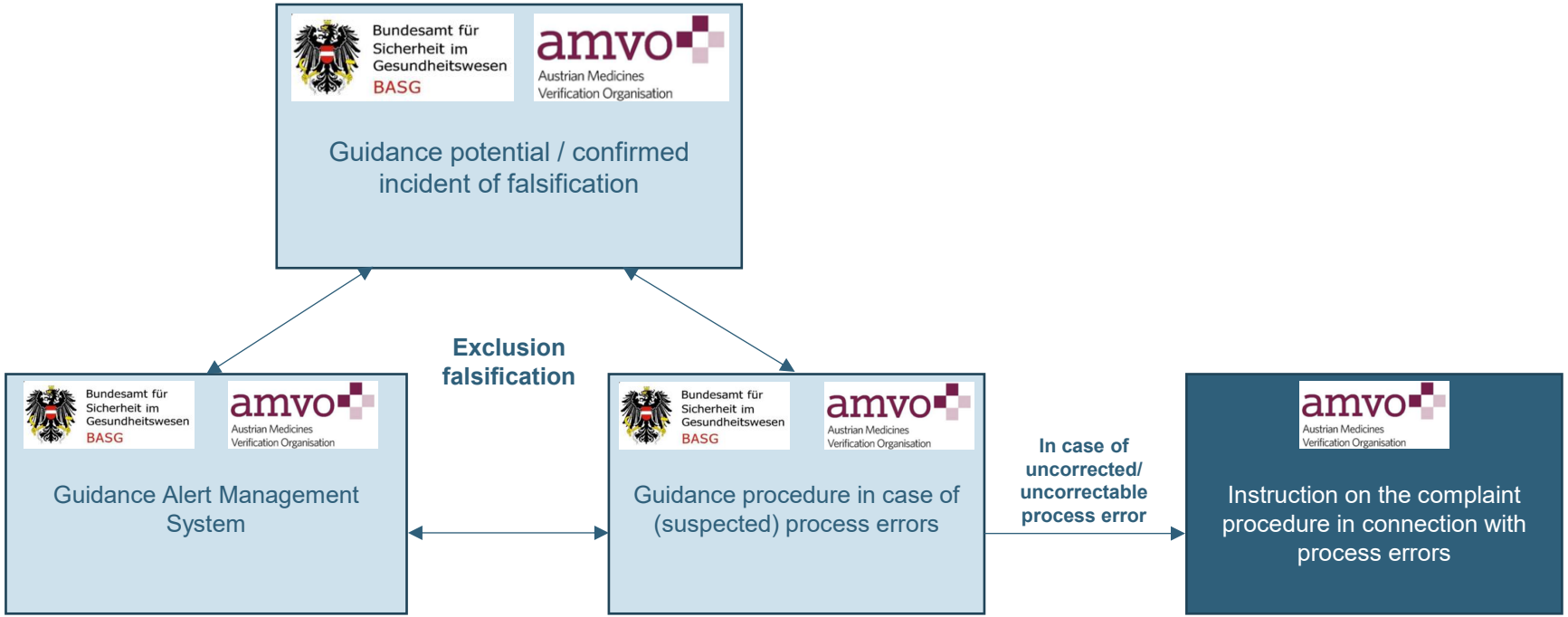
Correction of a process error (if applicable) must be done within 10 calendar days.

- Complaint possible if no correction is performed



Processes around Potential Incidents of Falsification after Start Phase

Austrian Medicines Verification System



Guidance potential / confirmed incident of falsification

Austrian Medicines Verification System

- Version 3 published in February 2025
- Reference to Alert Management System
- Adaption on EMVO Best Practice Guide on Alert Handling

Alerts that must be investigated by OBPs/MAHs:	Alerts that must be investigated on request of AMVS or BASG (NCA):	Alerts must be investigated if alert is generated by OBP himself / if OBP has decommissioned the pack himself / on request of AMVS or BASG (NCA):
A2 / NMVS_FE_LOT_03 / Batch not found A3 / NMVS_NC_PC_02 / Serial number not found A52 / NMVS_FE_LOT_12 / Expiry Date mismatch	A68 / NMVS_FE_LOT_13 / Batch number mismatch	A7 / NMVS_NC_PCK_19 / Pack already in requested state A24 / NMVS_NC_PCK_22, NMVS_NC_PCK_06, NMVS_NC_PCK_27 / Batch Status Missmatch

Guidance Alert Management System

Austrian Medicines Verification System

- Published in February 2025
- 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)
  - Communication with enduser is anonymised
  - Status of an alarm always at a glance

Guidance Alert Management System

Austrian Medicines Verification System

Investigation of alerts by OBPs/MAHs within 3 working days:

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

Guidance Alert Management System

Austrian Medicines Verification System

In case the Alert Managment System is not used:

- Procedure according Guidance potential / confirmed incident of falsification
- Investigation result must be submitted by Email within 3 working days to office@amvs.at

Process around Potential Incident of Falsification after Start Phase

Austrian Medicines Verification System

Duties of industry

Day 0

Within 3 working days: Feedback to AMVS / Exclusion of suspicion of falsification and if applicable information if and when the error will be corrected

Day 0 — Working Day 3 — Calendar Day 10

Within 10 calendar days: Correction of process errors

Correction process errors: Uploading of missing data

Undo of the decommission of mistakenly decommissioned packs

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Data Deletion

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Why Data Deletion?

- Amount of data in each NMVS is growing.
- Storage need in data centre / cloud.
- Database performance is expected to going down at a certain point.
- Reuse of serial numbers within the same product code by OBP based on delegated regulation 2016/161 Article 4d possible

„The character sequence resulting from the combination of the product code and the serial number shall be unique to a given pack of a medicinal product until at least one year after the expiry date of the pack or five years after the pack has been released for sale or distribution, whichever is the longer period."

Data Deletion

Austrian Medicines Verification System

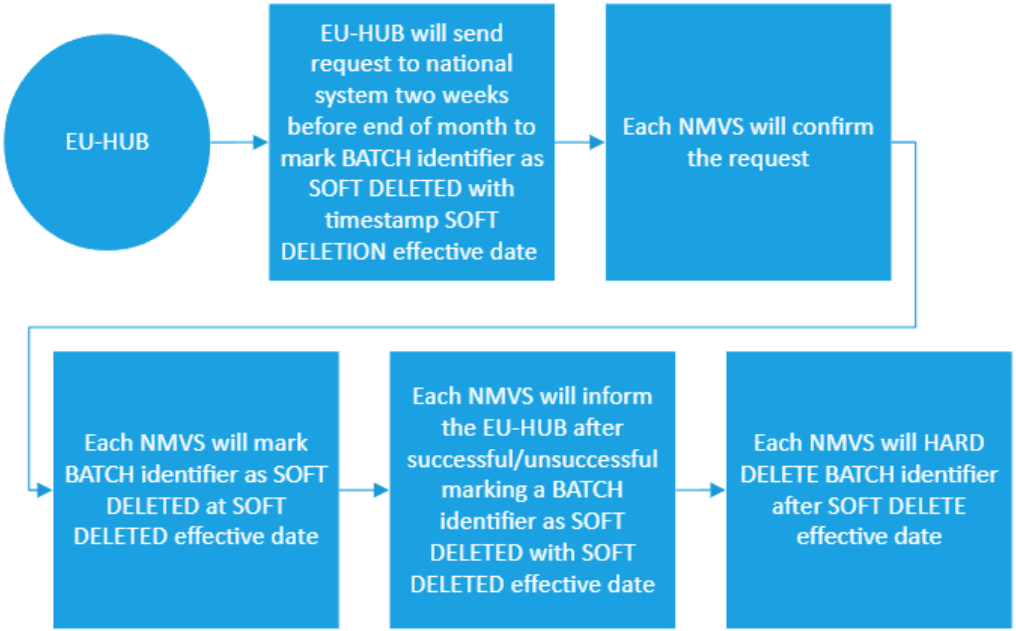
Which data will be deleted

- Pack data (based on delegated regulation 2016/161 Article 33 / 4)
  - Batch, Product, Pack will be deleted, at the end of the data retention period
  - The trigger will be the batch upload date or the expiry date (whatever is the longer) – which means that the packs related to a batch are all deleted at the same time, rather than being deleted individually
- Audit and Alerts data (based on delegated regulation 2016/161 Article 35 g)
  - Audit (transaction) data will be deleted, at the end of the data retention period
  - Alerts data will be deleted, at the end of the data retention period
  - The trigger will be the “creation” date of the Audit or Alert data

Data Deletion

Austrian Medicines Verification System

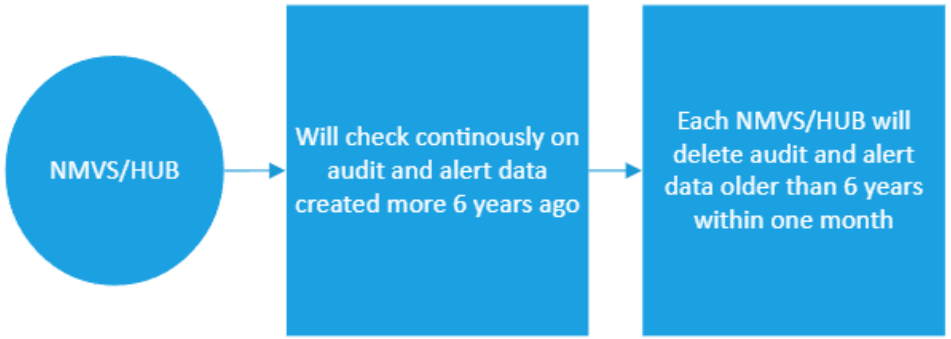
Batch Data Deletion - how it works



Data Deletion

Austrian Medicines Verification System

Audit and Alert Points deletion - how it works



AMVS goes Oracle Sovereign Cloud

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- Transfer of all data from Arvato Data Center to Oracle Sovereign Cloud
- Transfer was on 11.11.2025
- No impact on the pharmaceutical companies
- Even faster response times for end users can be expected, as system peaks can be balanced out.

Questions and Discussion

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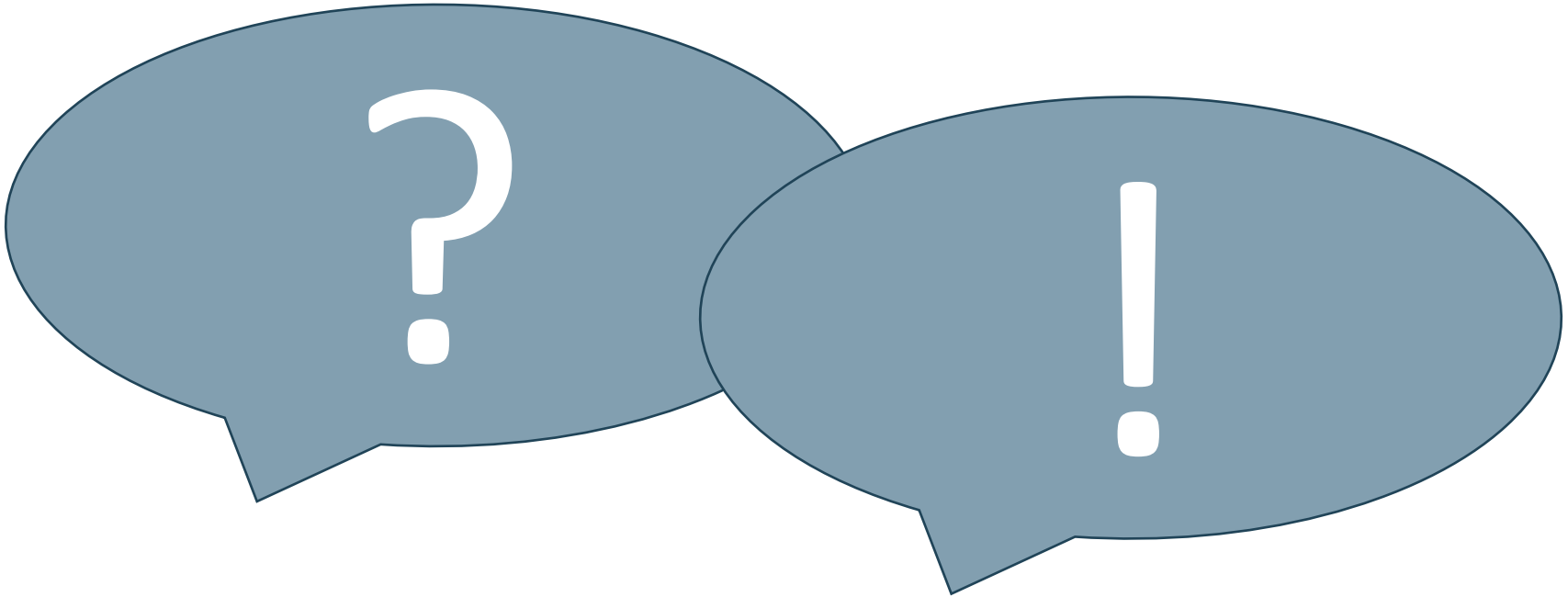
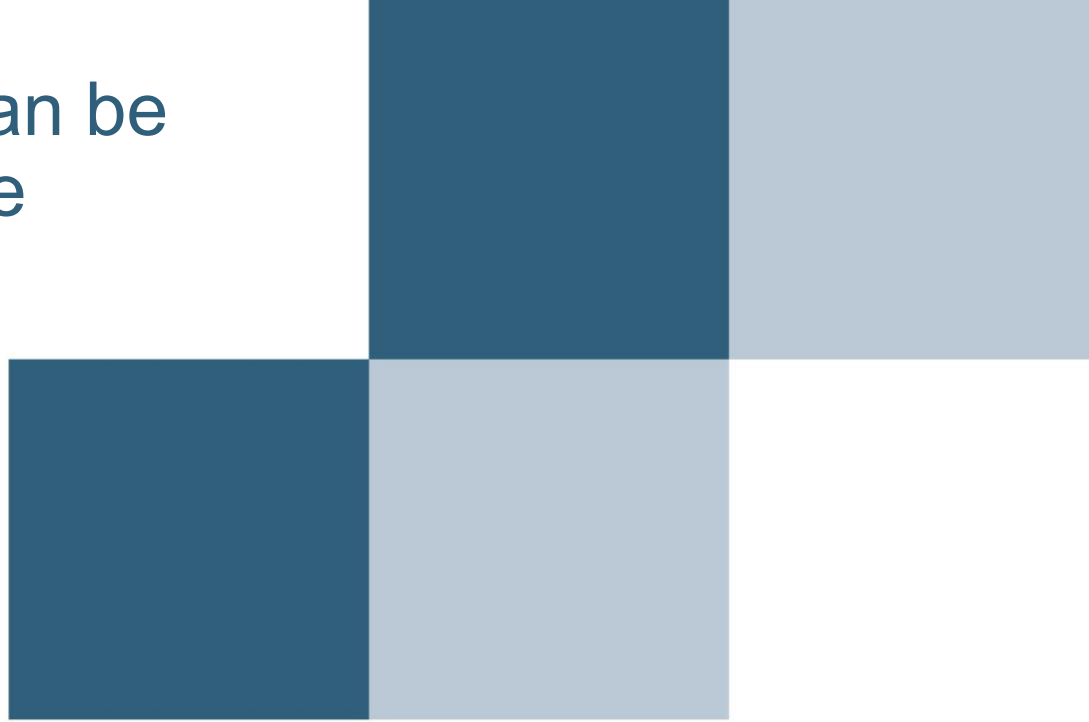


Current information can be found on our webpage https://www.amvs-medicines.at/en/ as well as our LinkedIn channel.



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

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