Information Event Pharmaceutical Companies

amvs
Austrian Medicines Verification System

Livestream Event

10.06.2021

Agenda

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Verification System

- AMVS Organisation
- Updated operational fees 2022 and status of contractual relations
- Coding Rules 4.0 and current recommendations
- Alert statistics und measures
- Startphase Operations
- New Guidelines for Operations

AMVS Organisation

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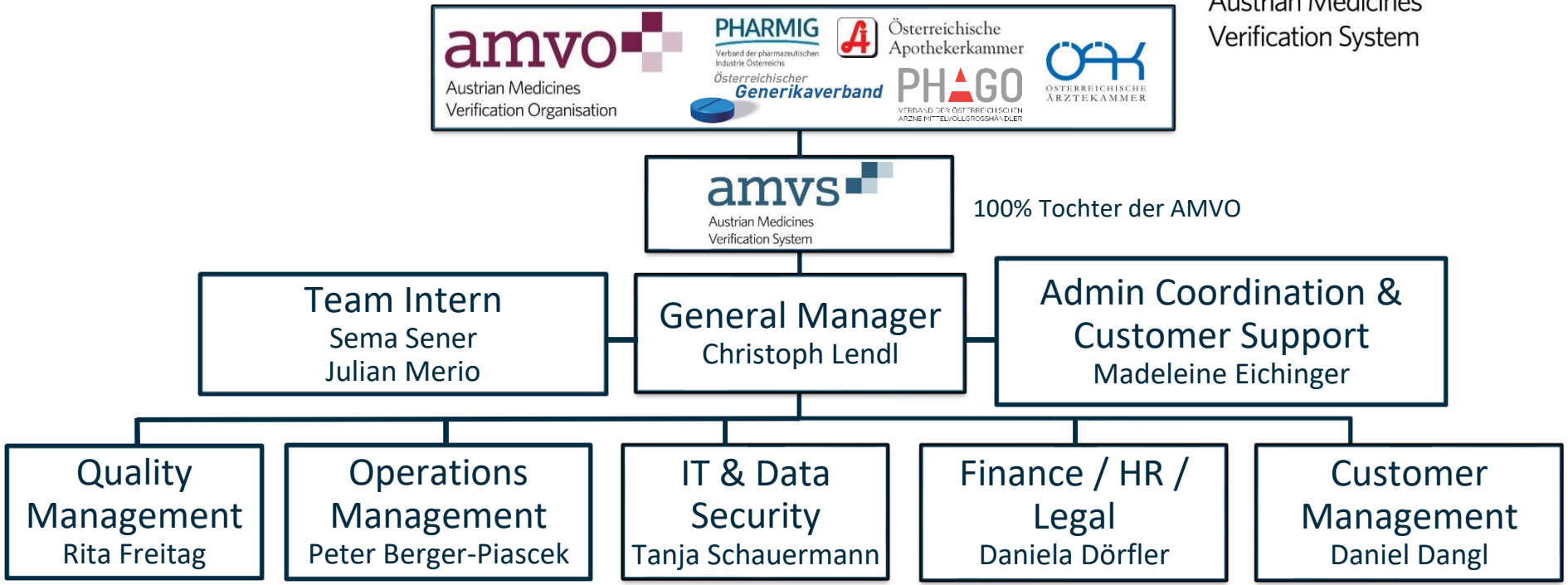

Conctractual Relations – Accession- and Service Agreement

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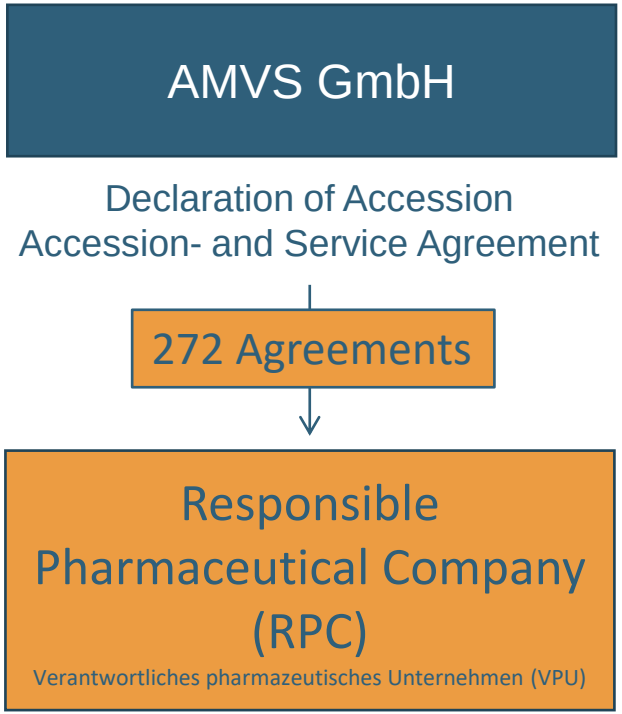

Status: 10.05.2021

Operational Fees
NEW Fee Model from 2022

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Fixed Turnover-based Part

- Reduction of the fee by 20%
- Introduction of 2 new turnover groups

Variable Volume-based Part

- Consolidation of three volume groups up to 2 Mio serial numbers / year

Operational Fee
NEW Fee Model from 2022

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Fixed Turnover based Part

Turnover € / User p.a.	Fee € / User p.a.	Fee NEW from 2022 € / User p.a.
< 100k	500	400
100k-3 Mio	3 000	
100k-1.5 Mio		1 200
1.5-3 Mio		2 400
3-10 Mio	5 000	4 000
10-30 Mio	15 000	
10-20 Mio		6 000
20-30 Mio		12 000
30-50 Mio	25 000	20 000
50-70 Mio	35 000	28 000
70-100 Mio	45 000	36 000
100-150 Mio	55 000	44 000
150-200 Mio	65 000	52 000
200-250 Mio	75 000	60 000
< 250 Mio	85 000	68 000

Operational Fee
NEW Fee Model from 2022

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Variable Volume-based Part

Price-Quantity Scale p.a.	€/serial number 2019-2021	€/serial number NEW from 2022
≤ 50.000	0,009	
50.001 - 500.000	0,008	
500.001 - 2.000.000	0,007	
≤ 2.000.000		0,007
≥ 2.000.001	0,004	0,004

Number of uploaded serial numbers based on AMVSystem

Contractual Relations Endusers - Technical Connection with AMVSystem

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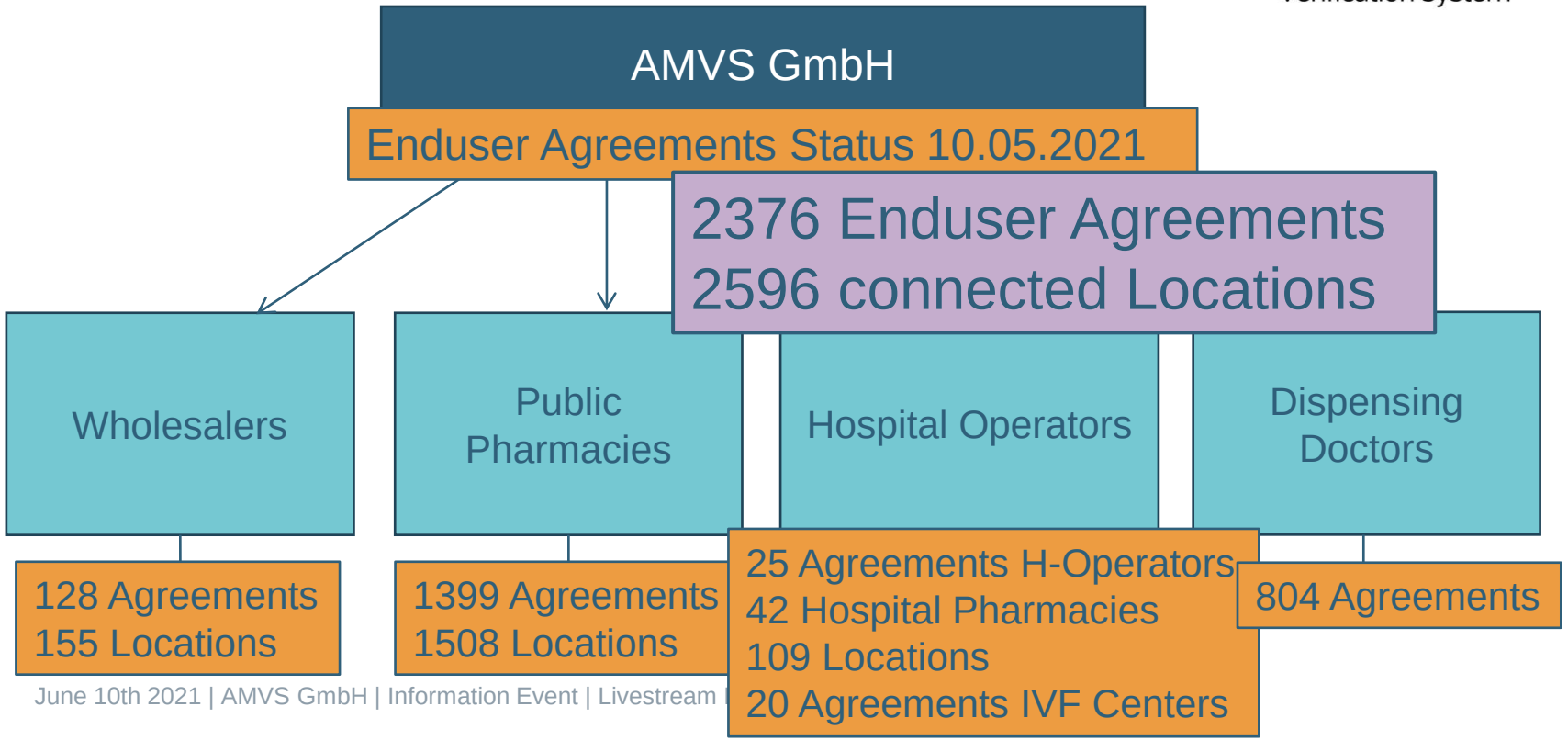
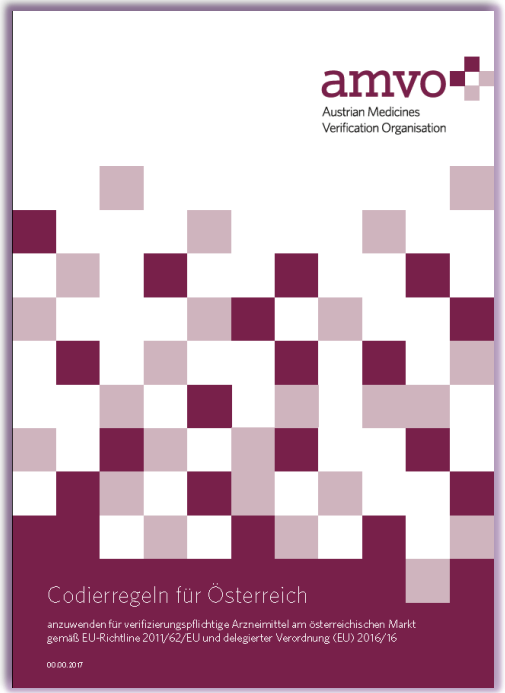


Coding Rules 4.0 and Current Recommendations



Version 1.0 published in October 2017
Version 2.0 published in April 2018
Version 3.0 published in March 2019
Version 4.0 published in November 2020

German Version:
https://amvs-medicines.at/FileDownload/4418
English Version:
https://amvs-medicines.at/FileDownload/4419

Coding Rules 4.0 and Current Recommendations

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Usage of the 1D-Bar Code

- Starting from February 9th 2019 the printing of the EAN-13 1D-Barcode is not required anymore

- Recommendation to no longer place on packs or remove in the course of planned changes to the packaging

Coding Rules 4.0 and Current Recommendations

Austrian Medicines Verification System

Remark regarding Upload of National Codes:

- The Austrian „Pharmazentralnummer“(pharmaceutical central number –PZN) must be uploaded using the EMVS Master Data Elements via the European Hub and stored in the national repository system

  (Field „National Code“ of the Market Specific Master Data Elements for Austria)
  - Pharmazentralnummer for Austria, 7-digits (incl. check digit)
  - For all Products
- A non- or incorrectly uploaded National Code can lead to problems in warehouse management (no or incorrect product information) for end users

Coding Rules 4.0 and Current Recommendations

Austrian Medicines Verification System

Recommendation regarding Character Set for Serial Numbers und Batch-ID:

- no usage of Y and Z
- no usage of special characters
  (batch-ID alphanumeric)
- usage of capital letters

Please refer to Q&As of EU Commission, current Version 18 from 12.08.2020

2.23. Question: Are there specific requirements for the characters used in batch and serial numbers?

Coding Rules 4.0 and Current Recommendations

Austrian Medicines Verification System

Further tips from the enduser’s experience

- DataMatrix code should not be located directly next to other codes (1D barcode, QR code). Ideally on another side
- Inverse DataMatrix codes should be avoided

Status of Productive AMVSystem Enduser Transactions and Alerts

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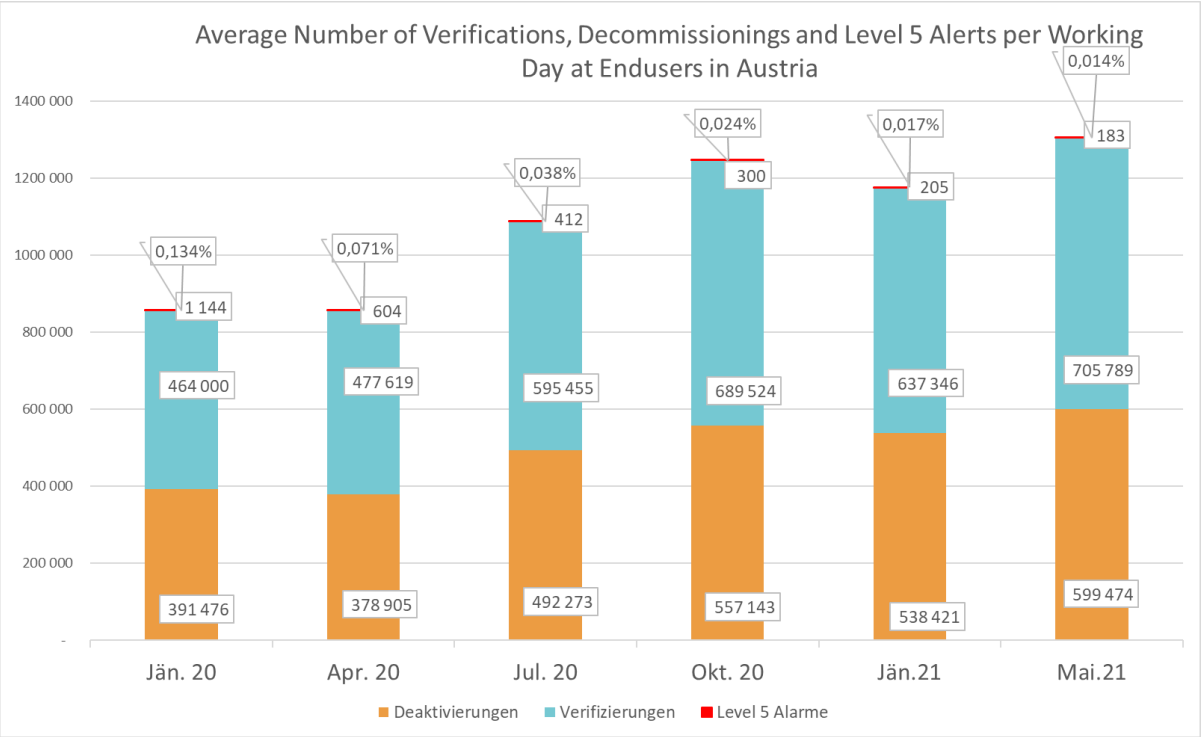

Numbers per Working Day without OBP-Alerts

Status Productive AMVSystem Enduser Alerts per Working Day

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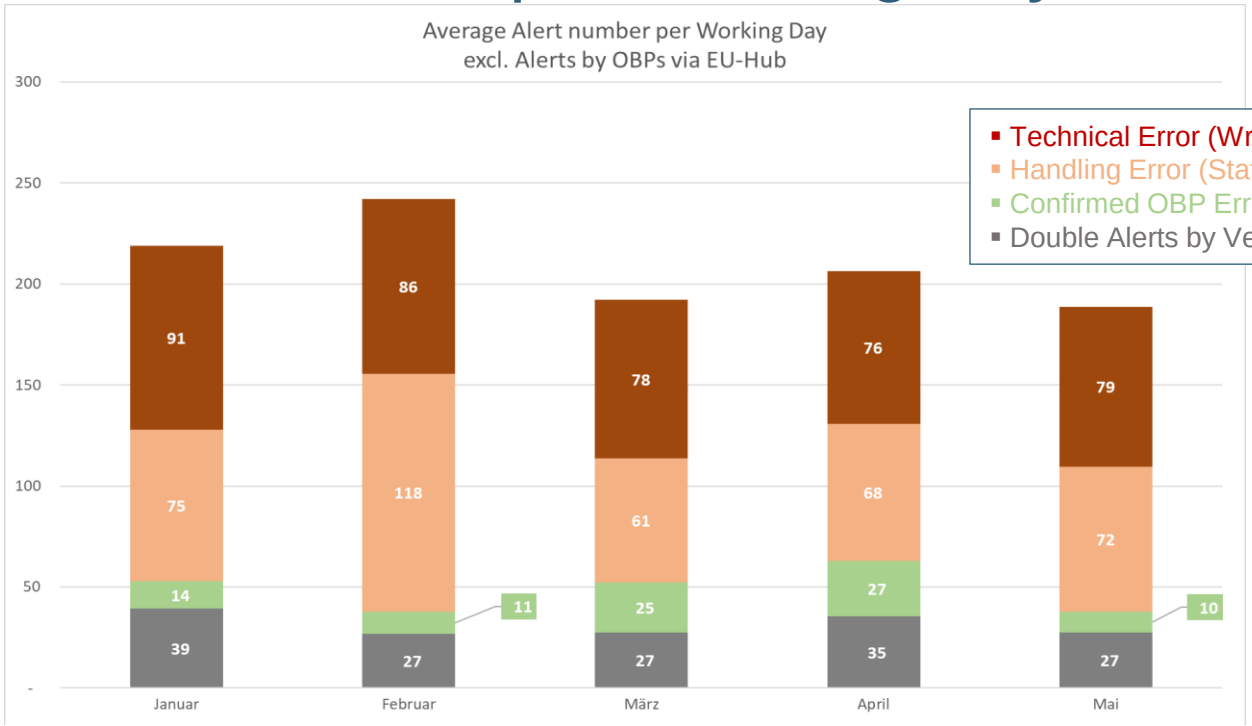

Weekly Alert Rates Compared across Europe

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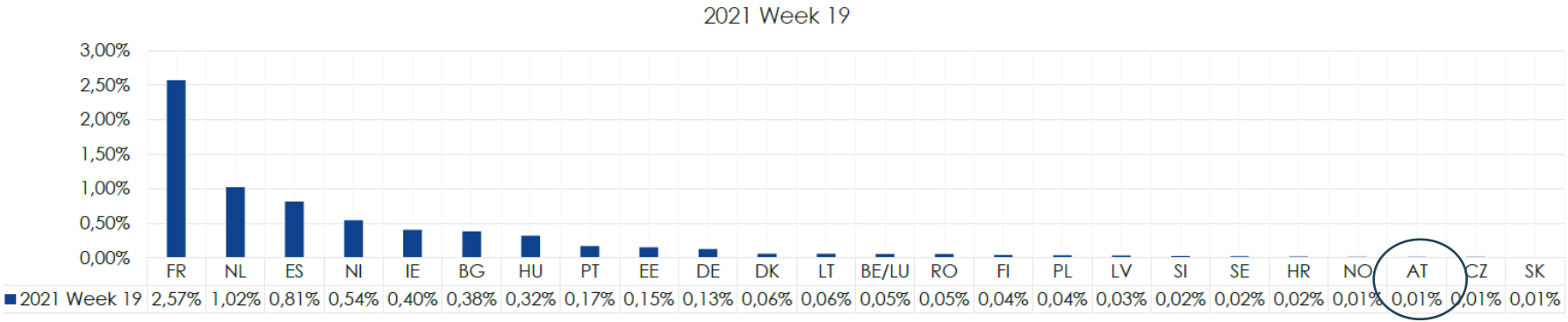

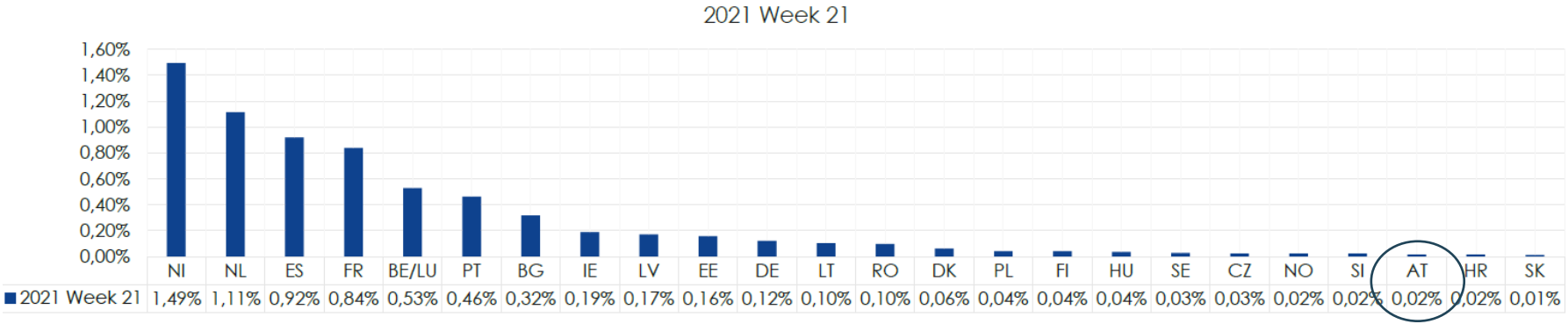

Alert rate incl. OBP-Alerts

Measures for Alert Reduction 2020/21

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Scanner Test Code for Endusers

https://amvs-medicines.at/infothek/presse-news/einfuehrung-eines-scanner-test-codes/

Measures for Alert Reduction 2020/21

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E-Mail Notifications on Level 5 Alerts

- October 2020 – January 2021
  one E-Mail per day including all alerts from the day before
- from February 2021
  one E-Mail per alert

Übergebene Alarmdaten	
Unique Alert ID	AT-67g3j0a-41j7-4c86-9u5s-15r653h89g5
Zeitpunkt des Alerts	Oct 20 2020 11:07AM
Arzneimittel lt. Warenverzeichnis	SUPERMED 5MG TBL
Produktcode	09088886587426
Charge	Z123
Haltbar bis	220531
Seriennummer	524789664475221
Aufgetreten bei	Abgabe einer Packung
Fehlercode	NMVS_FE_LOT_13
Fehlermeldung	Die Chargen Nummer ist anders als die im System hinterlegte.
Mandant	A-111888
Benutzer	A-9999-TESTAPO

Current Challenges – Industry

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Batch Release and delivery to endusers before upload - „Batch not found" error

Currently, approx. 1-2 batches per week which have yet to be uploaded are still being delivered to endusers

- Number of cases is constantly decreasing
- Correction (uploading of the batch) of the error usually takes place within 1-2 working days

Monitoring of alarms in this category by industry works very well

Further adaptation of quality systems which prevents delivery before uploading recommended

Current Challenges – Industry

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Non uploaded serial numbers –
Error „Serial Number not found“

Reasons e.g.:

- Data package of a partial batch has not been uploaded
- Individual serial numbers were excluded at the packaging line but packs were still brought to market

AMVS cannot distinguish wheter the serial number is missing in the system or a data retrieval missmatch took place

→ **Monitoring <u>of all alerts</u> and feedback to AMVS by industry**

After the start-up phase operations: correction of the error within 10 calendar days

Current Challenges – Industry

Austrian Medicines Verification System

Alert Management by OBP, MAH and RPC (VPU)

- OBP receives all Alert-Data via his EU-Hub Interface
- All alarms 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

After the start-up phase operations: Each alert must be analysed within 3 working days and the suspicion of falsification must be ruled out.

→ **Monitoring of <u>all alerts</u> and feedback to AMVS by industry**

Start Phase Operations from 09.02.2020

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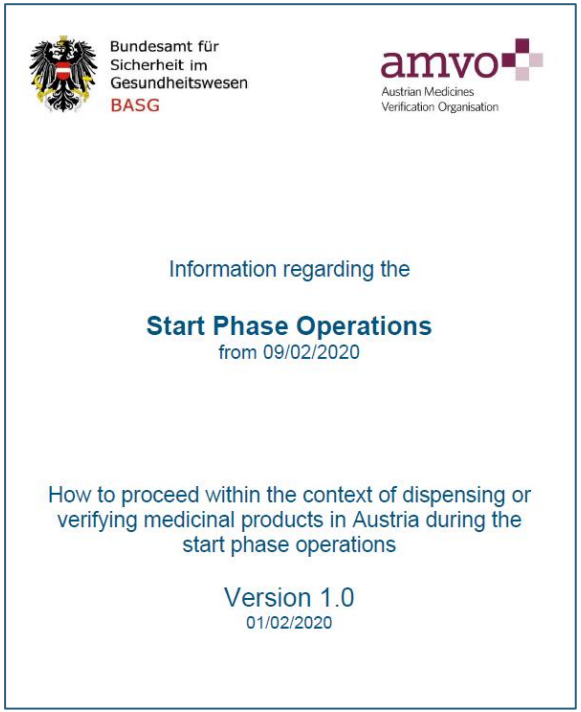
Endusers shall

- recognize technical and procedural errors
- optimize implemented processes

Error codes 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.



Start Phase Operations from February 9, 2020

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- Delegated regulation in place since February 9, 2019
- 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
- Implementation of next steps in autumn 2021
- End of start phase operations depends on the status of the pandemic

Processes around Potential Incidents of Falsification after Start Phase

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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

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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

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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
- 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

Guidance on Process Errors

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Classification in technical errors and in procedural errors

- Technical errors

  Errors in data correlation (batch, serial number, expiry date)

- Procedural errors

  Errors when requesting the pack status

Guidance on Process Errors

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Duties of industry

The confirmation of the process error and thus the exclusion of the falsification case must be completed and reported to AMVS within 3 (three) working days, as well as - if applicable - whether and when a corrective action will be taken

A possible corrective measure must be taken immediately, but in any case, within 10 calendar days from the generation of the first level 5 system message for the respective medicinal product pack

If a correction is not possible within 10 calendar days, the affected medicinal product pack must not be reintroduced into the saleable stock and the end user has the option to proceed according to the complaints procedure instruction

Guidance on Process Errors

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Duties of industry

Possible corrective measures

Technical errors:

- Uploading of the missing data (batch, serial number)
- Correction of incorrectly uploaded data (batch, expiry date)

Procedural errors:

- Re-commissioning of the pack (possible within 10 days from 1st decommissioning)

Complaint Procedure Instruction

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- Definition of complaint case
- Classification into case groups (assignment of cause)
- Consequences of the assignment

  The procedure, the handling and the (economic) consequences of the complaint depend on the respective contractual and business relationship between the enduser and the person or entity unequivocally identified as having caused the incident, as well as on the applicable statutory regulations.

Questions and Discussion

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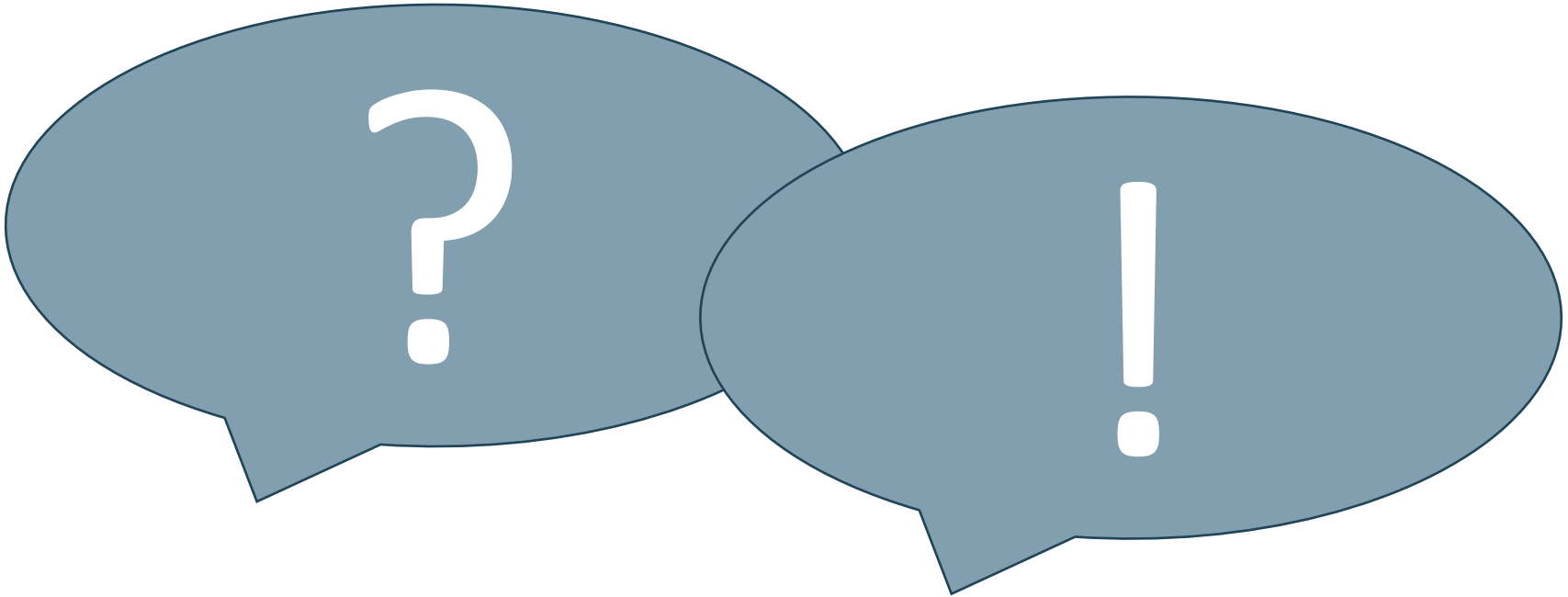

Current information can be found on our webpage https://www.amvs-medicines.at/en/ as well as our LinkedIn channel.

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

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