Information Event Pharmaceutical Companies

amvs
Austrian Medicines Verification System

Livestream Event

25.06.2020

Agenda

Austrian Medicines Verification System

- AMVS Organisation
- Status Contracts – Industry and Endusers
- Coding – Summary and frequently asked questions
- Alert Statistics and Actions
- Start Phase Operations
- Outlook on Time period after Start Phase Operations

AMVS Organisation

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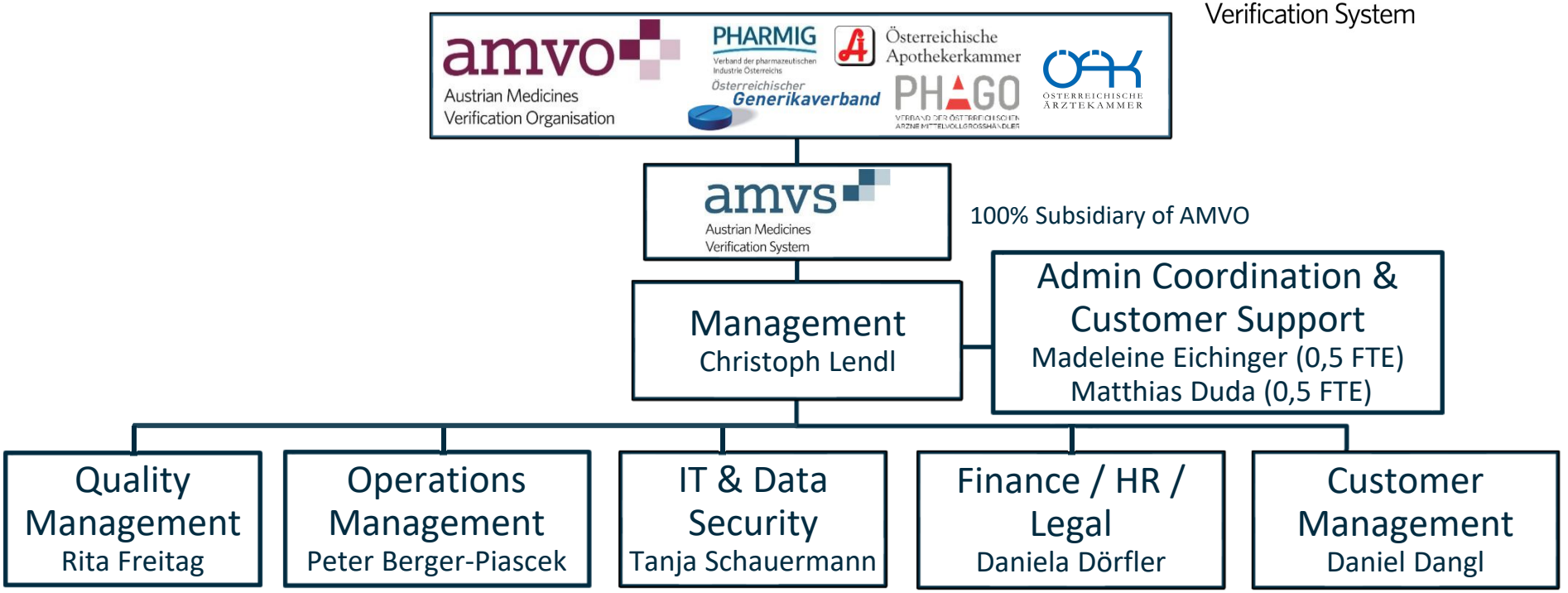
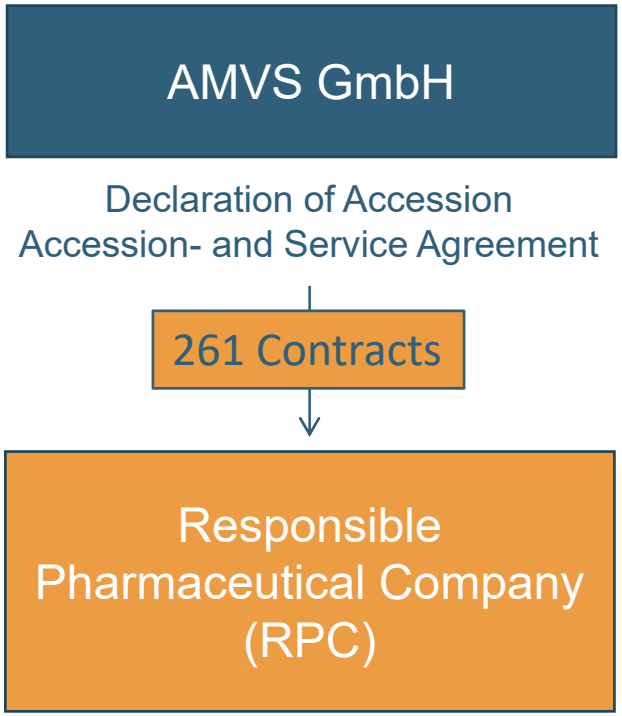


Conctractual Relations – Accession- and Service Agreement

Austrian Medicines Verification System



Status: 17.06.2020

Operational Fee 2020

Fixed Turnover based Part

Turnover € / User p.a.	Operational Fee € / User p.a.*
<100k	500
100k-3,0 Mio	3 000
3Mio-10 Mio	5 000
10-30 Mio.	15 000
30-50 Mio.	25 000
50-70 Mio.	35 000
70-100 Mio.	45 000
100-150 Mio.	55 000
150-200 Mio.	65 000
200-250 Mio.	75 000
>250 Mio.	85 000

01.12.2019 - 31.01.2020 (as well as any other year): Submission of turnover-category by form based on past calendar year

Invoiced by end of February latest

Payment due in 30 days

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EIGENEINSTUFUNG NUTZER GRUPPE VPU

Basis ist der *Nettoumsatz* für *serialisierungspflichtige Arzneispezialitäten* am österreichischen Markt des Vorjahres für die das *VPU* nach Punkt 3. des *Vertrages* verantwortlich zeichnet:

Firmenname VPU	
Vertragsnummer des Beitritts- und Nutzungsvertrages	VPU-

Nutzer Gruppen nach Nettoumsatz	Gebühr* € / Nutzer p.a.	
Nutzer Gruppe < 100k	500	☐
Nutzer Gruppe 100k-3 Mio	3 000	☐
Nutzer Gruppe 3-10 Mio	5 000	☐
Nutzer Gruppe 10-30 Mio.	15 000	☐
Nutzer Gruppe 30-50 Mio.	25 000	☐
Nutzer Gruppe 50-70 Mio.	35 000	☐
Nutzer Gruppe 70-100 Mio	45 000	☐
Nutzer Gruppe 100-150 Mio.	55 000	☐
Nutzer Gruppe 150-200 Mio.	65 000	☐
Nutzer Gruppe 200-250 Mio.	75 000	☐
Nutzer Gruppe > 250 Mio.	85 000	☐

* Der *fixe-Anteil* der *Nutzungsgebühr* gemäß Punkt 6.1.a) kann sich gemäß Punkt 6.3. ändern. Über die jeweilige Änderung der Anpassung der *Nutzungsgebühr* informiert die *AMVS GmbH* in schriftlicher Form (z.B. über Rechnungsaufdruck).

Wir erklären hiermit, dass die oben angeführten Daten richtig und vollständig sind und die vorgenommene Eigenstufung den *Nettoumsatz* für unsere *serialisierungspflichtigen Arzneispezialitäten* am österreichischen Markt, entspricht

Ort, Datum

Firmenmäßige Zeichnung
(Firmenstempel, Unterschrift, Name in Druckbuchstaben)

Basis are medicinal products obligated to serialisation in Austria.
*Net in Euro

Operational Fee 2020

Austrian Medicines Verification System

Variable Volume based Part

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

Degressiv calculation of the volume based part per year

Basis are the number of uploaded serial numbers into the AMVSystem
*Net in Euro

Key date:

- ✓31. March
- 30. June
- 30. September
- 31. December

Invoice latest by:

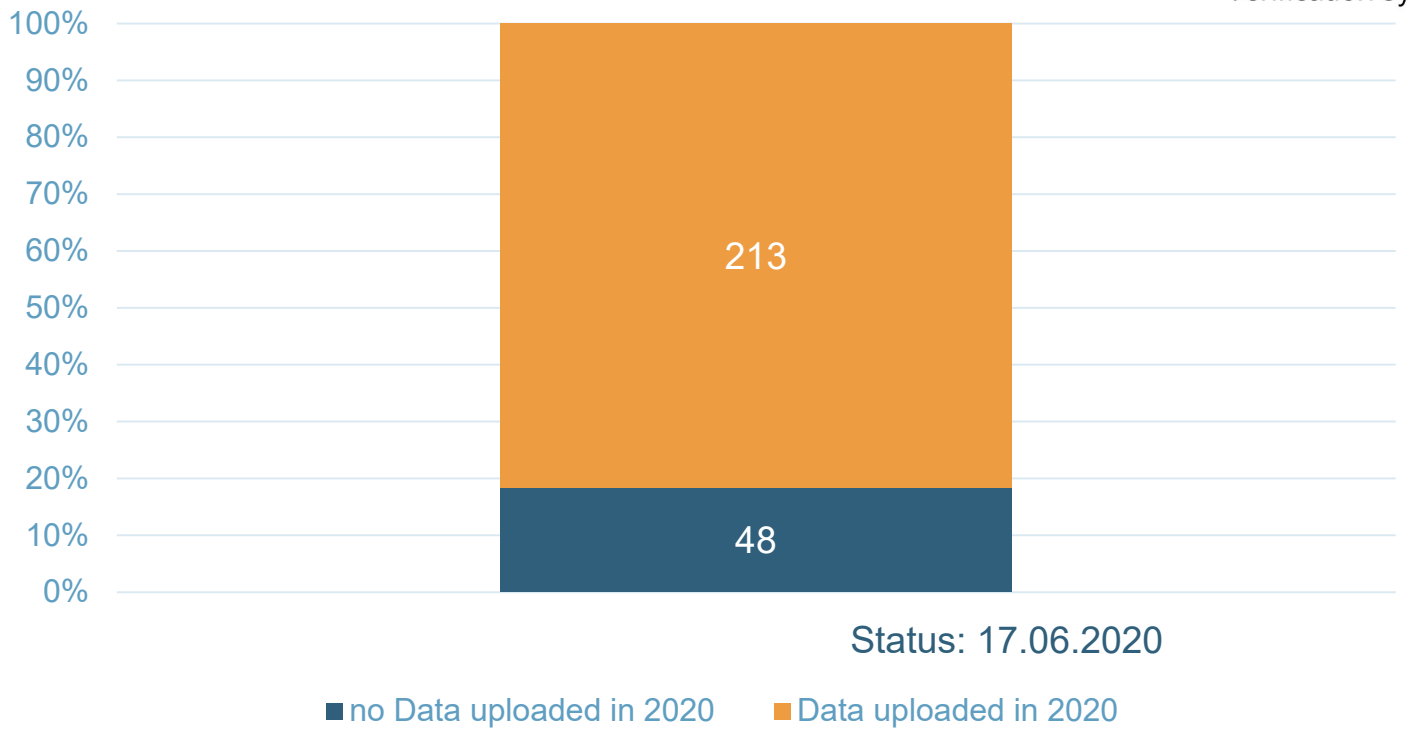
- 30. April
- 31. July
- 31. October
- 31. January

Payment due in 30 days

Behavior RPCs

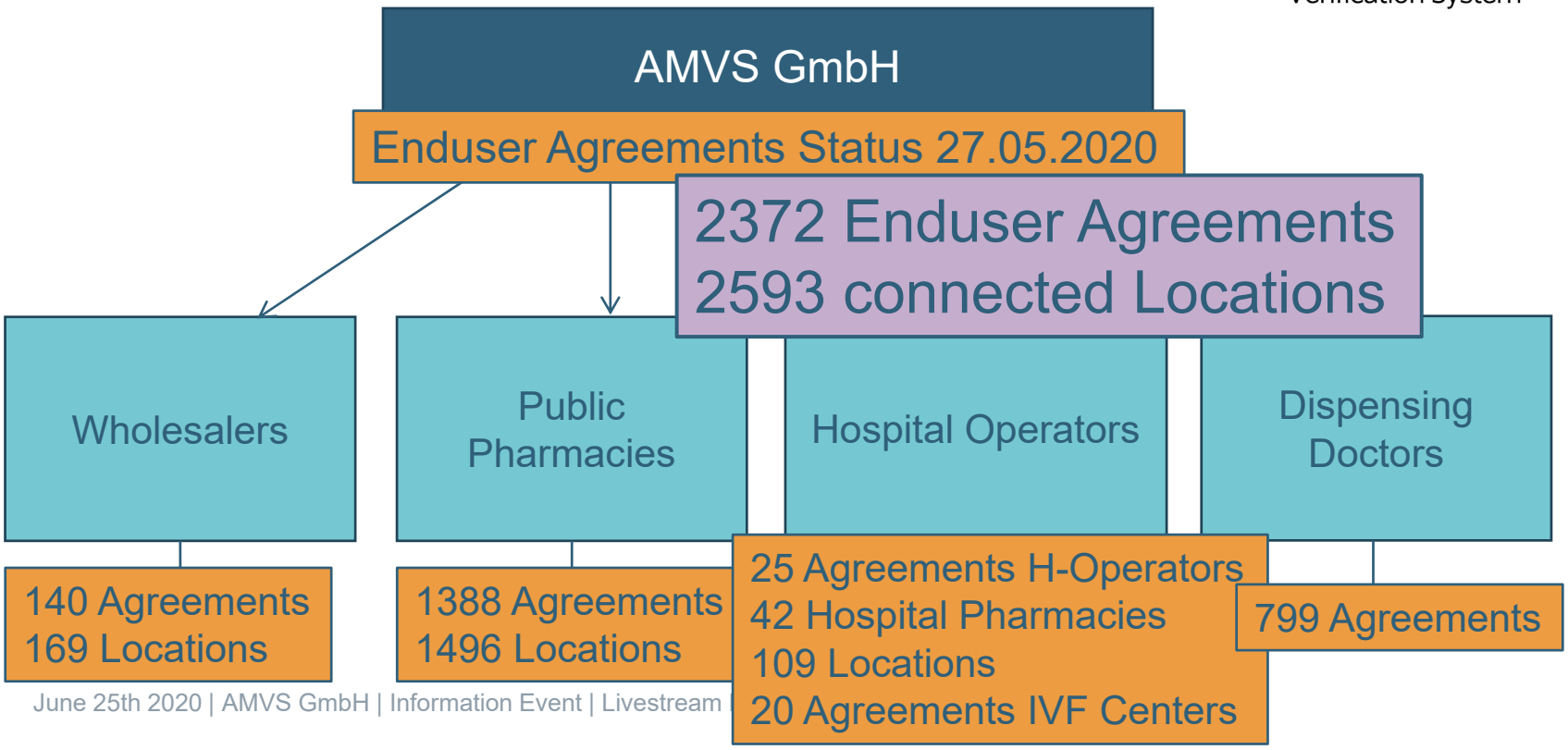
Austrian Medicines Verification System

Data related to 82% of RPCs were uploaded so far in 2020



Contractual Relations Endusers - technical connection with AMVSystem

Austrian Medicines Verification System



Coding – Summary and Frequently Asked Questions

Austrian Medicines Verification System

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

https://www.amvs-medicines.at/FileDownload/3473
https://www.amvs-medicines.at/FileDownload/3474

Coding

Austrian Medicines Verification System

Usage of the 1D-Bar Code

By Feb. 9th 2019 is the printing of the EAN-13 1D-Barcode not required anymore.

Until further notice the EAN-13 1D-Barcode may retain.

Coding

Austrian Medicines Verification System

Single Market Product:

- NTIN is used as Product Code (starting with 0908888…)

Multi Market Product:

- Generally GTIN is used as Product Code
- Use of an NTIN of a different country as Product Code:
  - As long as there are no other country specific numbers used in the 2D Data Matrix Code
  - Data Matrix Code without 5th Element

Coding

Austrian Medicines Verification System

Upload of Multi Market Packs:

- Art. 33 Abs. 1 del Reg: The information shall be stored in all national repositories serving the territory of the Member State or Member States where the medicinal product bearing the unique identifier is intended to be placed on the market.

- No upload in repositories where the medicinal product is not placed on the market.
  This also applies for centrally authorised products
  In particular there is no upload required for packs that are brought to Austria in context of the „Arzneiwareneinfuhrgesetz“ (medicinal products import act)

Coding

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

Coding

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Remark 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

Coding

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Q&As of EU Commission, current version 17 from 09.03.2020

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

Answer: No. However, in order to reduce the risk of false alerts due to end-user scanner misconfigurations, manufacturers are strongly encouraged to follow the recommendations below.

Serial and batch numbers should preferably:

- Contain only uppercase letters;
- Not include special characters (eg. hyphens, question marks, etc.); and
- Avoid the use of the letters "I", "O", "Y" and "Z".

Coding

Austrian Medicines Verification System

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Austrian
Federal Office for
Safety in Health Care
BASG

Communication from the Federal Office for Safety in Health Care concerning the obligations of the manufacturers placing safety features pursuant to Delegated Regulation (EU) 2016/161

- Taking into account the observations set out under 2.23 in the Q & A document of the European Commission concerning the particular requirements relating to the characters used in batch IDs and serial numbers.

Coding

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Potential wrong inquiries when using special characters

Example: Batch ID A33/01

Wrong Interpretation by Scanner / Software:

A33-01

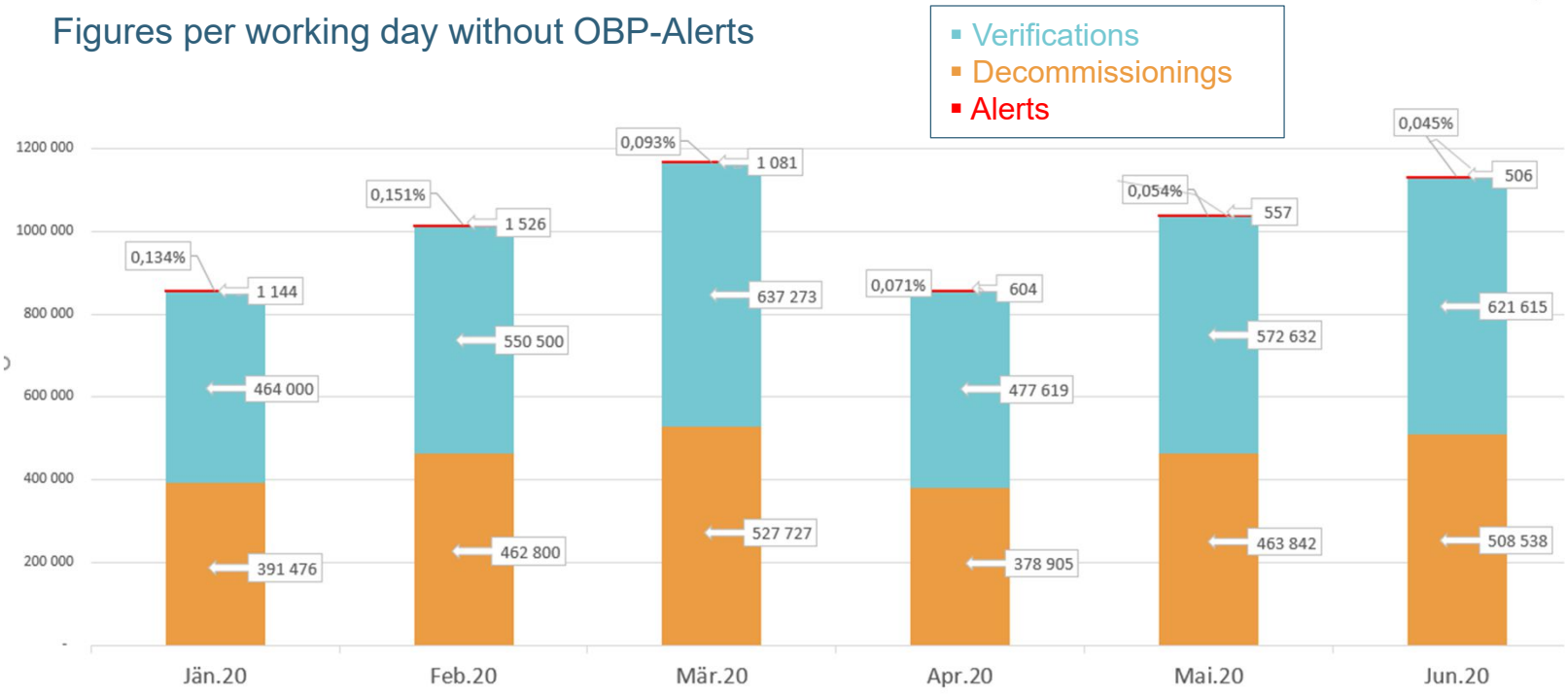
A33701

A33

Status productive AMVSystem
Enduser Transactions and Alerts

Austrian Medicines Verification System

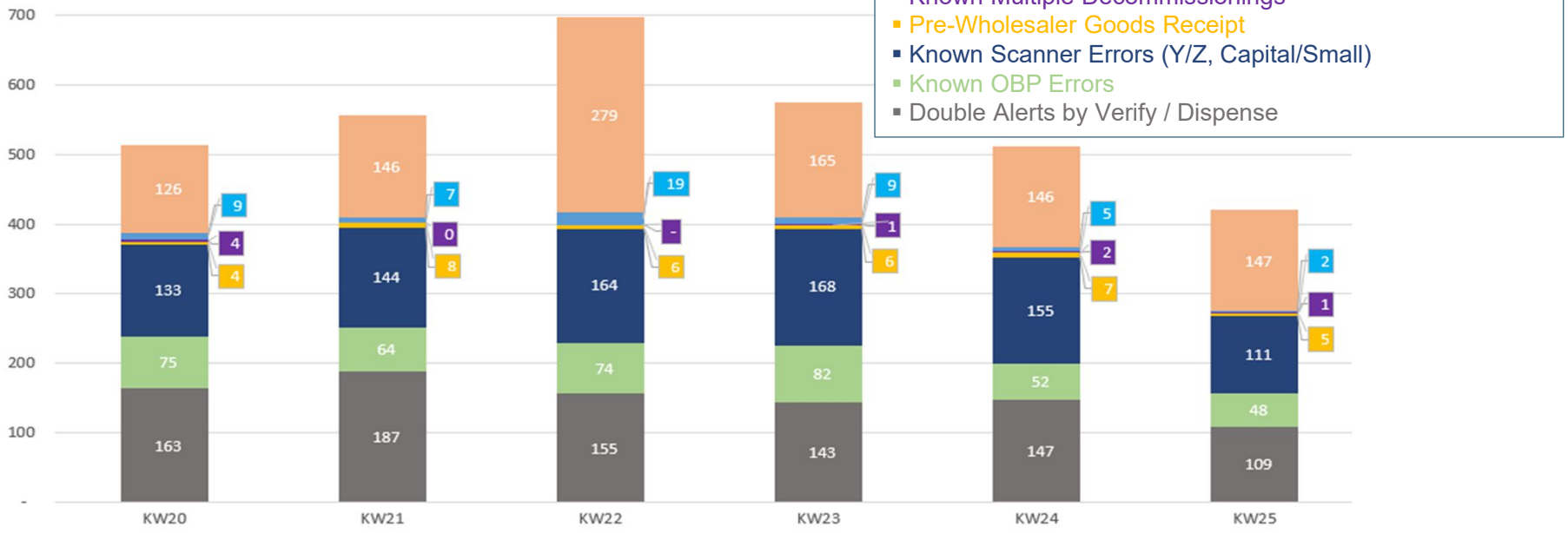
Figures per working day without OBP-Alerts



Status productive AMVSystem Enduser-Alerts per Working Day

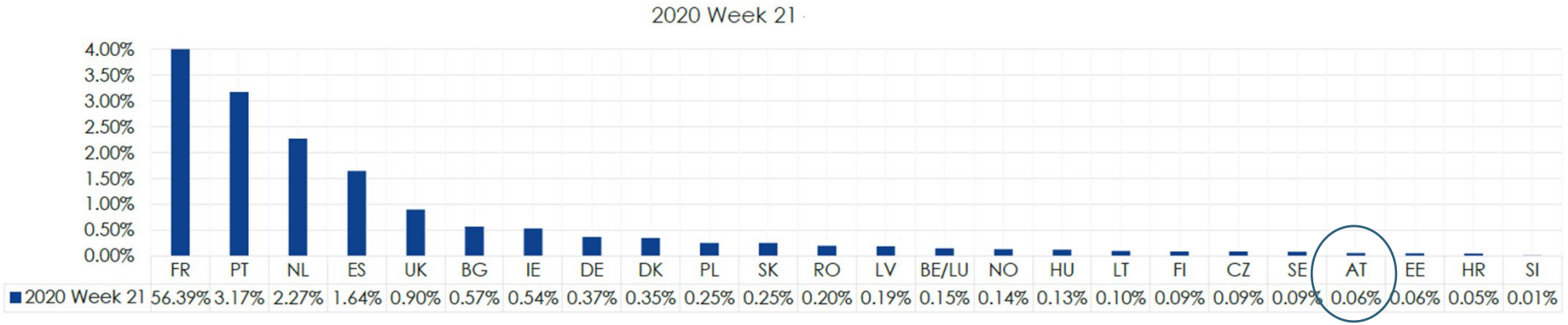
Austrian Medicines Verification System

without OBP-Alerts



Weekly Alert Rate in Europe

Austrian Medicines Verification System



Alert Rate incl. OBP-Alerts

Actions performed by AMVS

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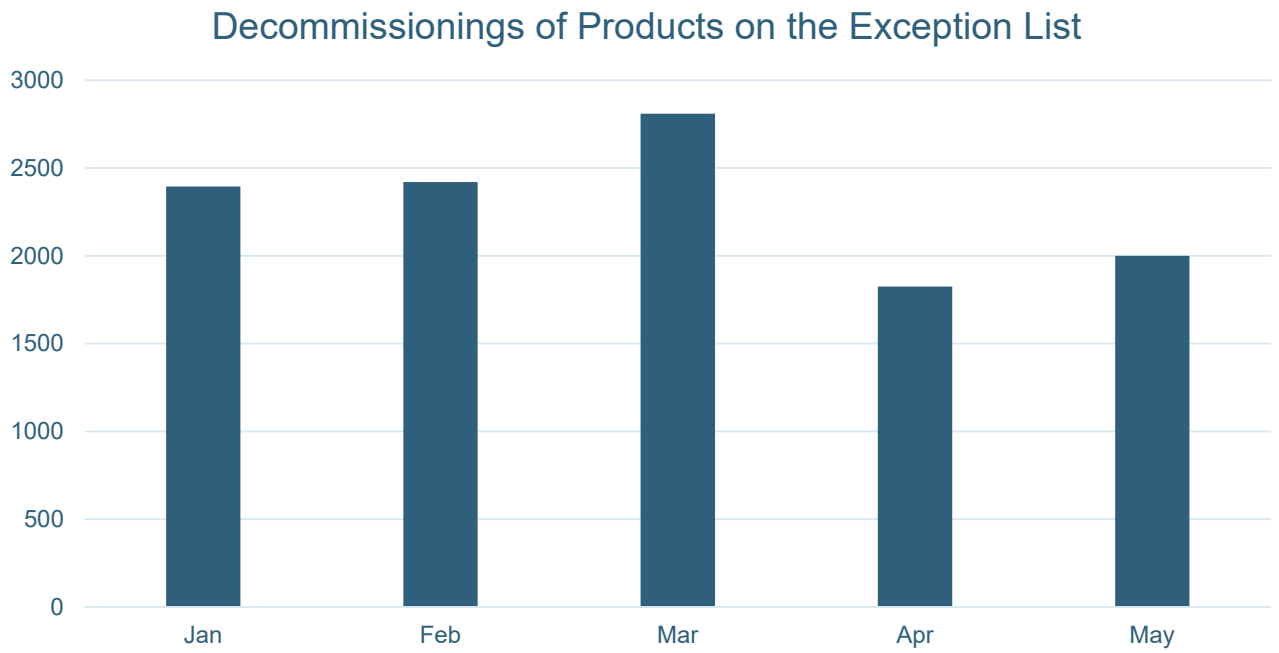
Cause	Affected	Actions
Indian Packs	RPCs	Exception list by 12/2019
Expiry Date Matching	Endusers / RPCs	By Autumn 2020: Match only YYMM
Errors by Data Upload	RPCs	Information Events, Direct Contacting
Scan Configuration	Endusers	Information Events, OnePager, Testscan with Reference Code, Direct Contacting of Endusers and Software Suppliers
Double Decommissionings	Endusers	Information Events, One Pager, Direct Contacting of Endusers
Not / less active Endusers	Endusers	Information Events, Direct Contacting by AMVS and Chambers

Actions performed by AMVS
Exception List Indian Packs

Austrian Medicines Verification System



Notification in case of Error-Messages

Austrian Medicines Verification System

How do I as RPC/VPU get notifications on error-messages?

- OBP has to be registered for the EMVO-Webservice
- RPC to get in contact with the OBP / the OBPs
- Forwarding of the Austrian error messages to the RPC by the OBP (starting with AT-…)

Current Challenges – Industry

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Communication from the Federal Office for Safety in Health Care concerning the obligations of the manufacturers placing safety features pursuant to Delegated Regulation (EU) 2016/161

- Paying particular attention to checking the completeness of the uploaded data in the repository prior to the first delivery to Verifying and Dispensing Locations.
- Recommendation to perform random checks of the uploaded data for correctness (batch number, expiry date).

Current Challenges – Industry

Austrian Medicines Verification System

Error „Serial Number not found“

Reasons:

- Data package of a partial batch has not been uploaded
- Individual serial numbers were segregated at the packaging line but the packs were brough on the market

AMVS cannot distinguish if the serial number is missing in the system or if there is a missmatch in data retrieval.

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

Current Challenges – Industry

Austrian Medicines Verification System

Error „Pack has been decommissioned already “

entire batch decommissioned by OBP:

- destroyed*
- batch recall*
- sale items as free sample

product withdrawn from the market*

→ **Clarification with BASG required on how to proceed with this batch**

*irreversible

Start Phase Operations from 09.02.2020

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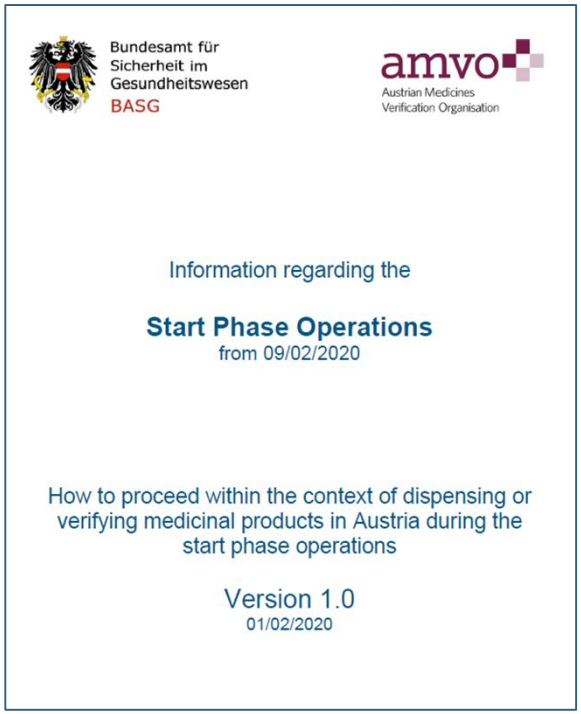
Endusers shall

- recognize process and handling 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.


Bundesamt für Sicherheit im Gesundheitswesen
BASG

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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

Start Phase Operations from 09.02.2020

Austrian Medicines Verification System

- Delegated regulation since 09.02.2019 in place. 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, first target figures have been met.
- Launching of next implementation steps in autumn 2020.

Start Phase Operations from 09.02.2020

Austrian Medicines Verification System

Bundesamt für Sicherheit im Gesundheitswesen
BASG

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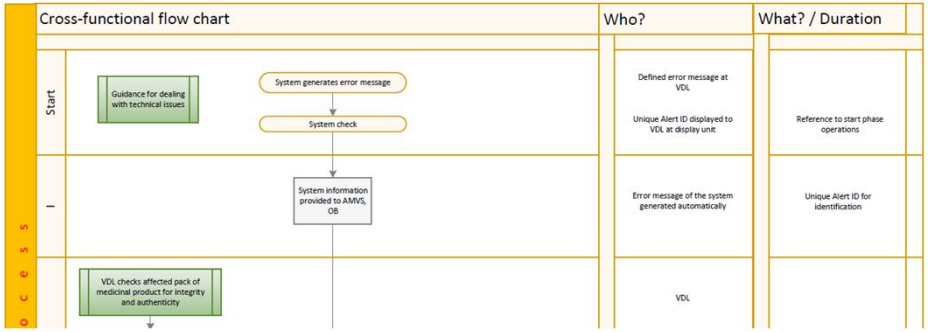
Start Phase Operations (from 09/02/2020)



https://amvs-medicines.at/infothek/startphase-echtbetrieb/

https://www.amvs-medicines.at/en/infothek/start-phase-operations/

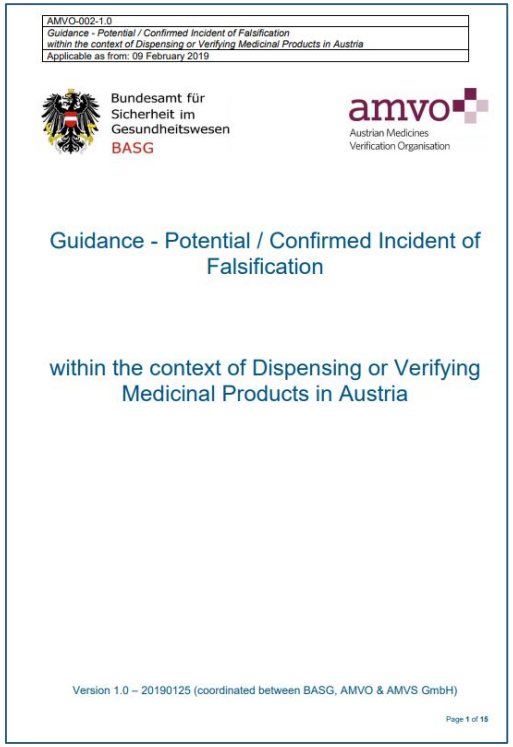
Process Potential Incident of Falsification after Start Phase

Guidance - Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria

Version 1.0

Published 25.01.2019

Austrian Medicines Verification System


AMVO-002-1.0
Guidance - Potential / Confirmed Incident of Falsification within the context of Dispensing or Verifying Medicinal Products in Austria
Applicable as from: 09 February 2019

Bundesamt für Sicherheit im Gesundheitswesen BASG

amvo Austrian Medicines Verification Organisation

Guidance - Potential / Confirmed Incident of Falsification

within the context of Dispensing or Verifying Medicinal Products in Austria

Version 1.0 – 20190125 (coordinated between BASG, AMVO & AMVS GmbH)

Page 1 of 15

Start Phase Operations – Time after Start Phase

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Bundesamt für Sicherheit im Gesundheitswesen
BASG

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BASG

Communication from the Federal Office for Safety in Health Care concerning the obligations of the manufacturers placing safety features pursuant to Delegated Regulation (EU) 2016/161

- Proactive cooperation with AMVS upon occurrence of alert messages, especially as regards ruling out technical errors and process errors in accordance with the information regarding the start phase operations.

Start Phase Operations – Time after Start Phase

Austrian Medicines Verification System

Duties of Industry

Analysis of all incoming error messages

- Was the affected pack of medicinal product serialised correctly?
- Have pack details been uploaded completely and correctly to the EMVS?
- Is there any process error and/or operator error?

Start Phase Operations

Feedback to AMVS on potential root cause under office@amvs-medicines.at

After the Start Phase

Feedback to BASG and AMVS on potential root cause under serialisierung@basg.gv.at and office@amvs-medicines.at

Process Potential Incident of Falsification after Startphase

Austrian Medicines Verification System

Duties of Industry

- Within 3 (three) working days the ruling out of process faults has to be completed and the error corrected (e.g. Upload der fehlenden Daten, Korrektur der fehlerhaften Daten).
- BASG informs the enduser that no incident of falsification is present. BASG has to decide whether the affected pack
- has to be treated as a case for complaint;
- will be sampled by BASG;
- can, in cases the error has been corrected, be released for supply to the public.

Process Potential Incident of Falsification after Startphase

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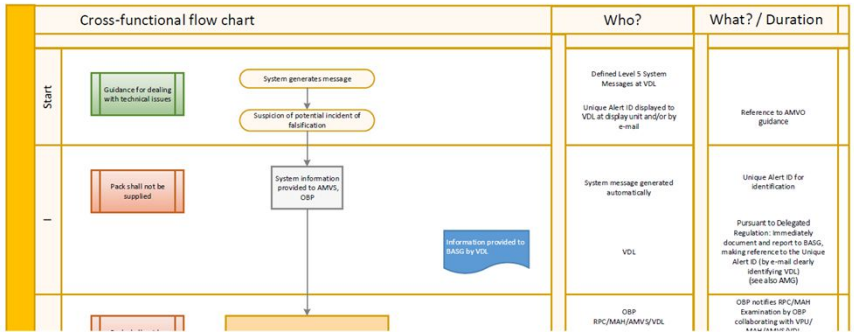
Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Guidance - Potential / Confirmed Incident of Falsification



https://amvs-medicines.at/infothek/leitlinie-potenzieller-bestaetiger-faelschungsfall/

https://www.amvs-medicines.at/en/infothek/guidance-potential-confirmed-incident-of-falsification/

Questions and Discussion

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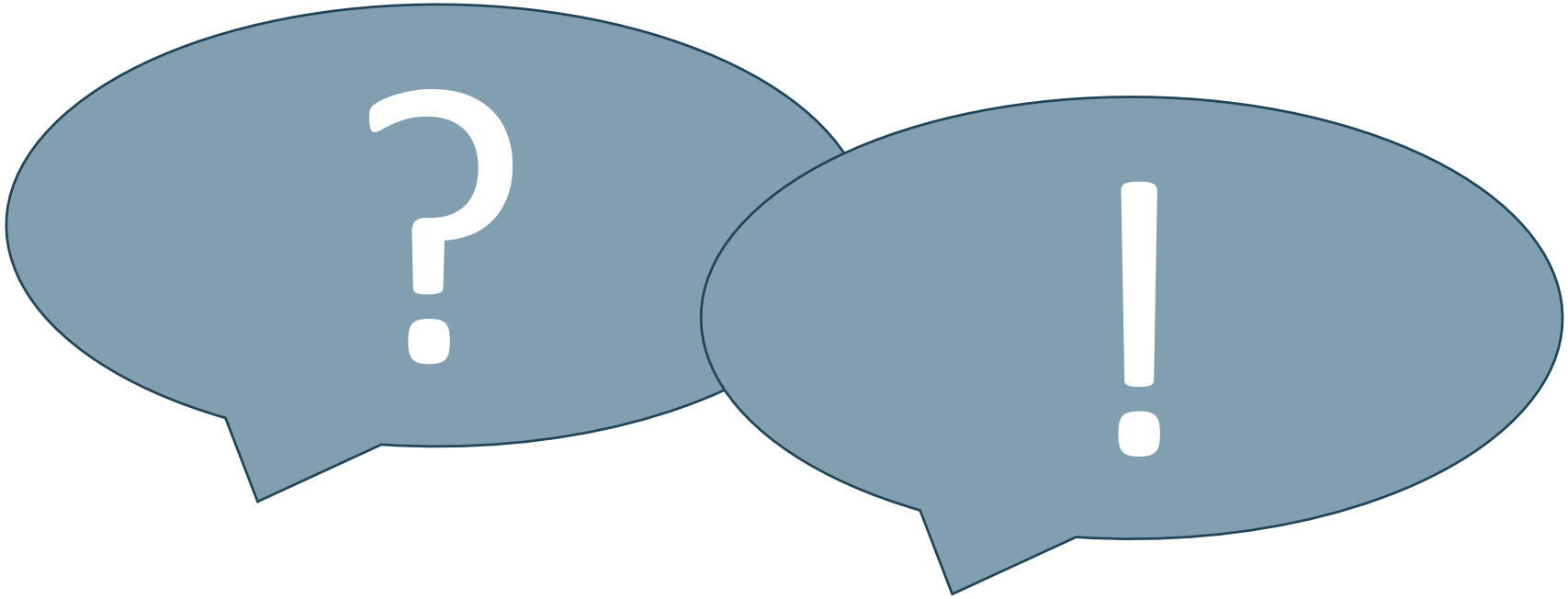

Thank you for your participation!

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

DISCLAIMER

Austrian Medicines Verification System

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