DMVO Dansk Medicin Verifikation Organisation

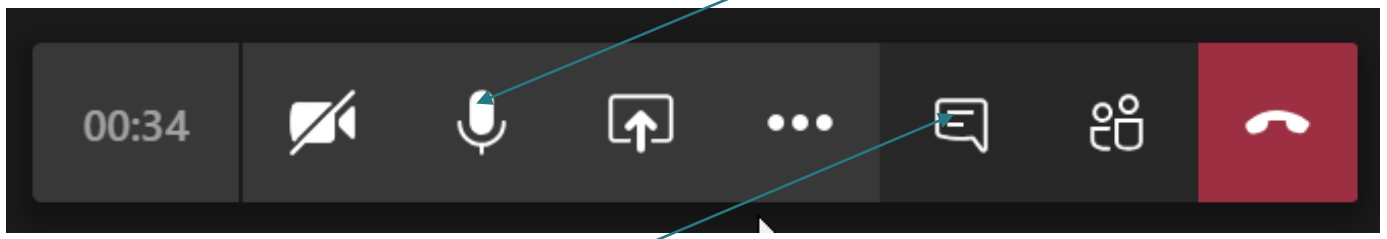
Danish Medicine Verification Organisation

Virtual Meeting 26.05.2020

DMVO´s alert handling procedure for Marketing Authorisation Holders

THE HOUSE RULES of DMVO during virtual meeting

- All participants are on mute by default to reduce noise
- Unmute yourself by clicking on the microphone icon



- Feel free to ask questions during the meeting
- Chat comments are always welcome
- The meeting will be recorded and made available for download and later review

DMVO

Danish Medicines Verification Organisation

Danish Medicines Verification Organisation

- Patient safety in collaboration with other national stakeholders and the NCA.
- Ensure an operational and well-functioning verification system in Denmark in full compliance with the Falsified Medicines Directive(FMD).
- Focal point of Contact for questionaries regarding the FMD.

DMVO

Virtual meetings

- Why:
  - Survey
  - Transparency
  - Direct communation /dialogue with stakeholders
- What:
  - Different topics/themes based on needs/questionnaries
  - English
  - Open for suggestions
- When:
  - Monthly meeting
  - Morning – same time 8.30 – 9.15.
- Where:
  - Virtually
- How to join:
  - Sign up by sending an email to info@dmvo.dk – everyone is welcome to join

DMVO

DMVO´s alert handling procedure for OBP/ Marketing Authorisation Holders

Walk through and overview of the alert handling procedure:

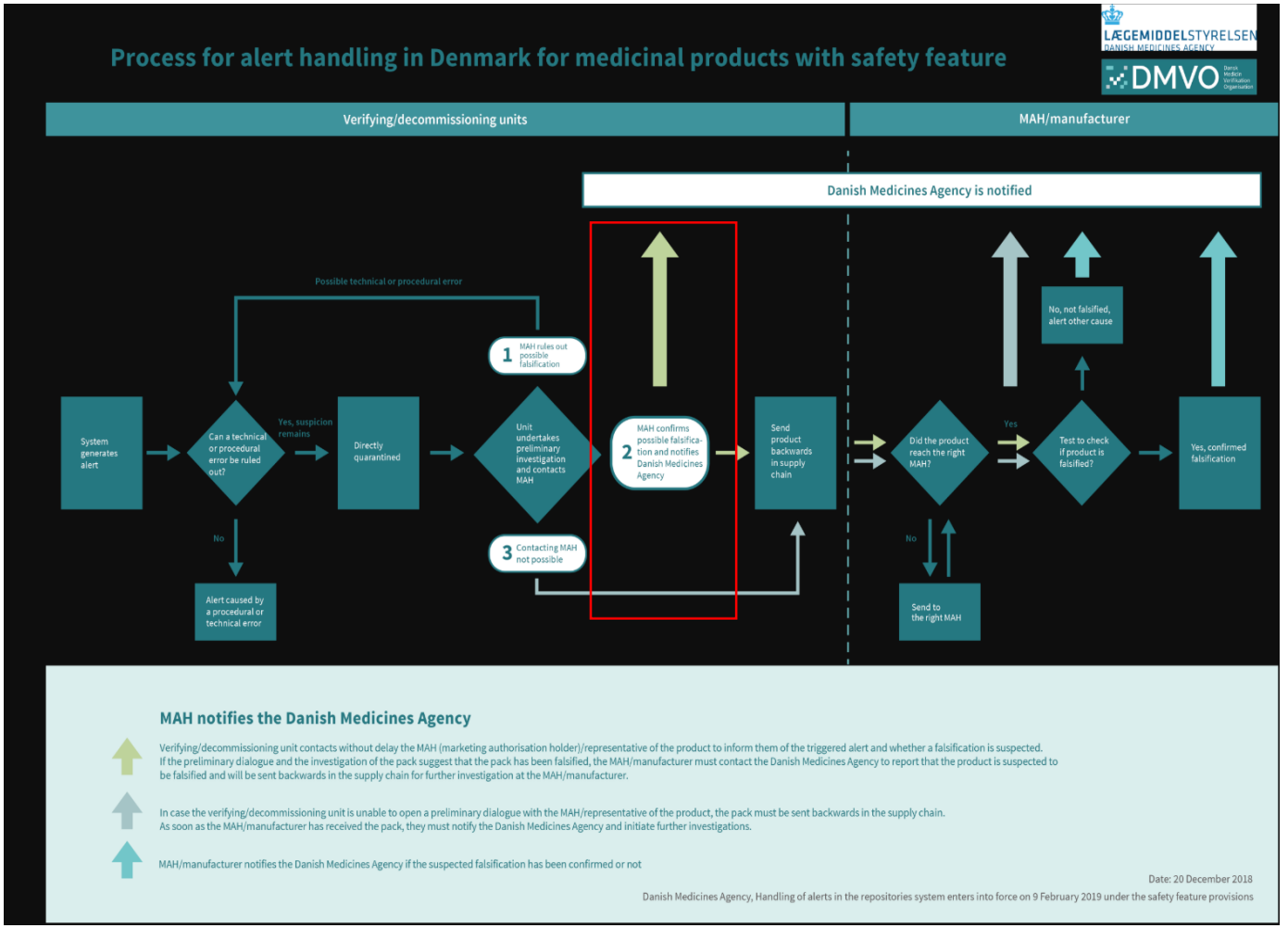
- Verifying one pack per batch
- Duty to report
- How to investigate an alert?
- DMVO´s information needs when investigating alerts
- Expected response time

Verifying one pack per batch

- One pack per batch shall be verified by the Onboarding Partner/ MAH, before release to the market with the aim of securing data is correct and uploaded to the European Hub (EMVS).
- This is done by scanning one pack per batch

Duty to report to the Danish Medicines Agency

- There is duty to report any findings of medicinal products that are or may be falsified medicinal product packs to the Danish Medicines Agency.



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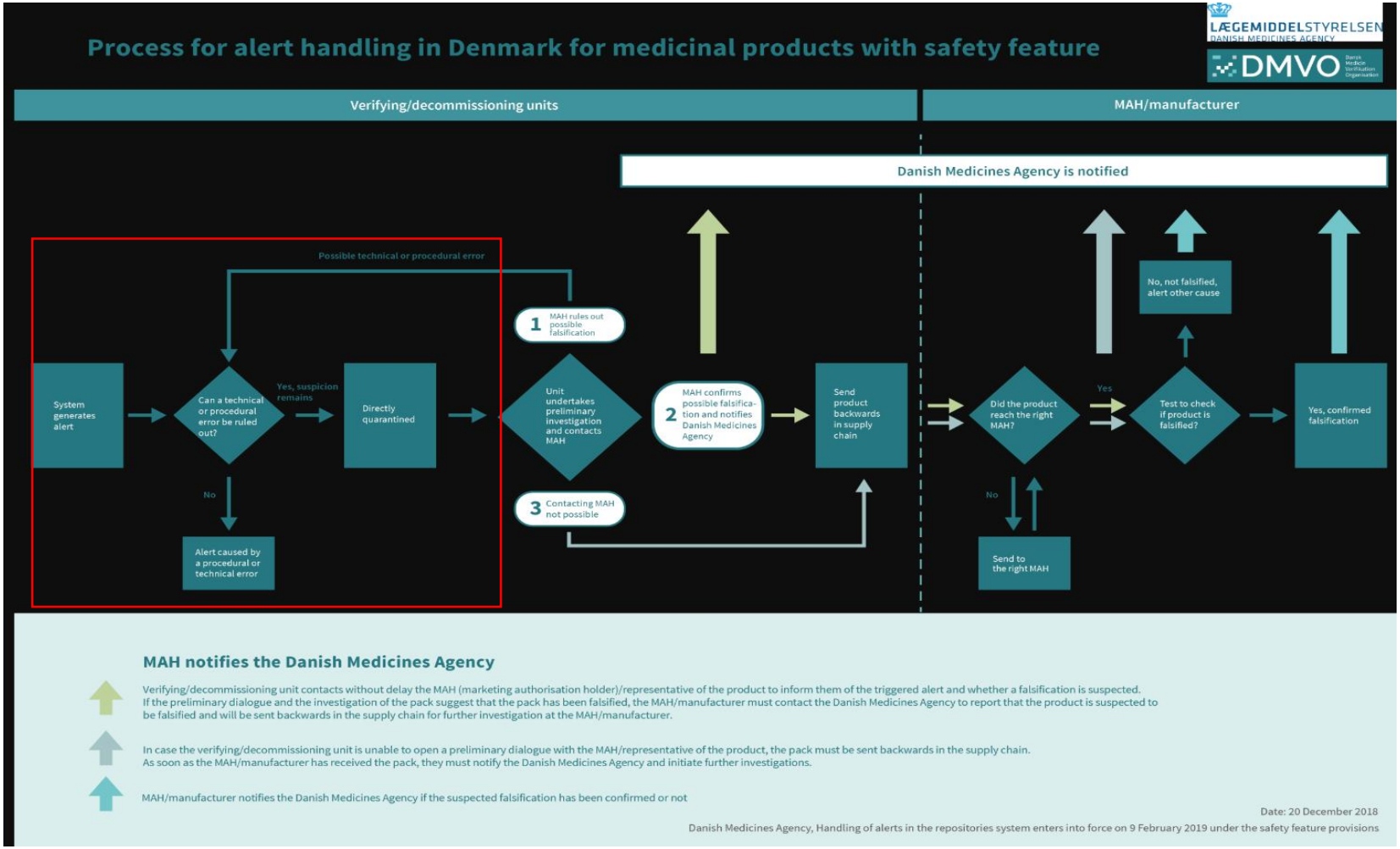
DMVO´s alert handling procedure for OBP/ MAH



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Step 1: How to investigate an alert?

- **Data error**: Is data uploaded correctly? Data uploaded to the European Hub must match what is printed on the pack.
  - This applies to: batch number, expiration date, serial number GTIN number and 2D data matrix code

- If an alert occurs, it must be investigated whether it may be due to a technical or procedural error.

There are several factors that can cause the alert:

- Misconfigured scanner(s)
- Cap locks on keyboard is turned on which "reads" incorrectly.

Step 2: How to investigate an alert?

Suspected falsification:

- If a technical and procedural error can be excluded, and there is a suspicion of falsified medicine, it must be reported to the **Danish Medicines Agency**; rapidalert@dkma.dk

Emergency lines

- On Boarding Partners (OBPs) are obliged to have a line open: phone & email for the supply chain to be able to communicate in case of necessity.
- DMVO recommends that MAH's points out an alert contact person reachable for DMVO.
- Kindly send name, email and phone number of the contact person to info@dmvo.dk

DMVO´s information needs when investigating alerts

Kindly provide following mandatory information to info@dmvo.dk:

- Alert Id
- Batch number (LOT/Batch)
- Product code (PC/GTIN)
- Expiry date (EXP)
- Contact person

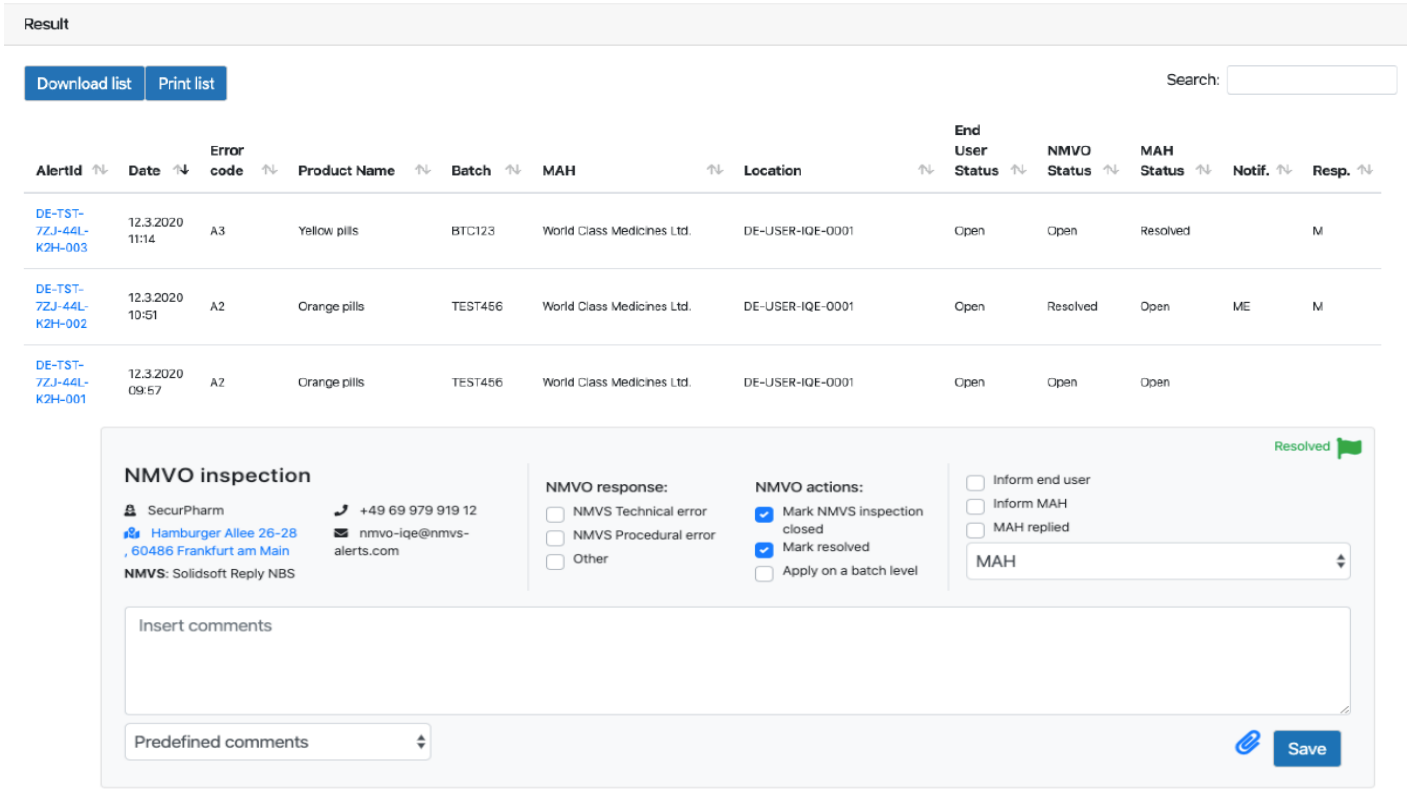
Additional highly recommendable information:

1) Serial Number (SN)
2) Picture of the 2D Data matrix code from identical same batch

The alert handling system of DMVO:

nmvs alerts

- “NMVS Alerts” is an automated tool for displaying alert information and performing investigations.



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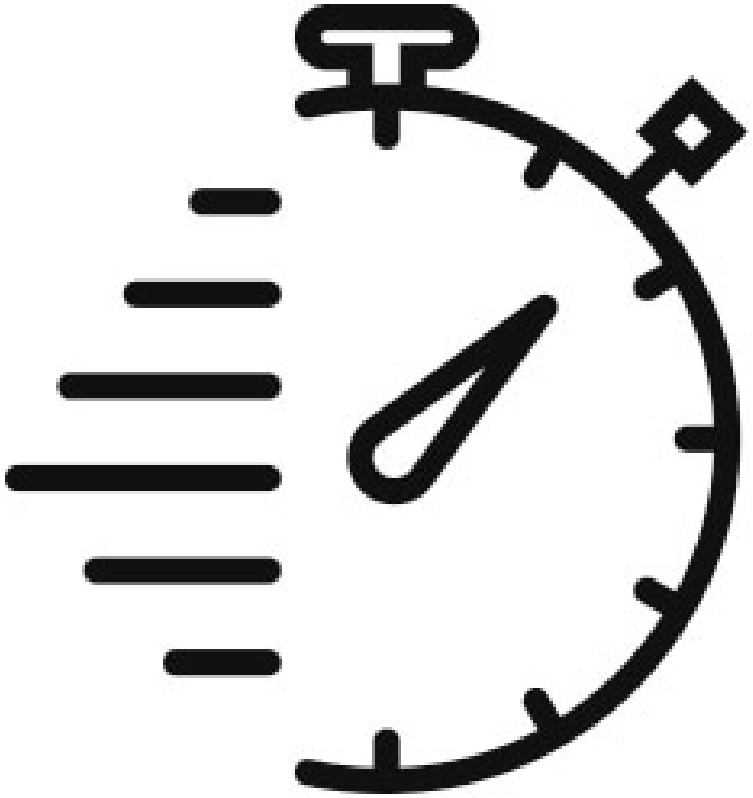
Expected response time

The expected response time from the first DMVO inquiry is **3** working days.

The expected correction time on incorrect data is also 3 working days.



Question time!

Thank you for your participation!

DMVO