

Danish Medicine Verification Organisation

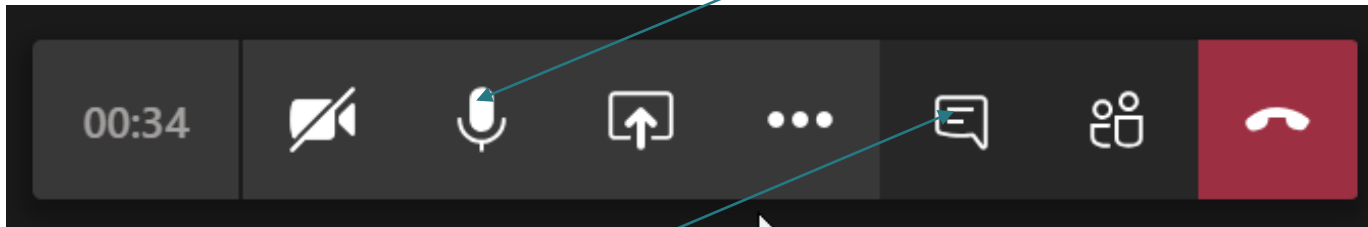
Virtual Meeting 26.05.2020

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

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 questionnaires regarding the FMD.

Virtual meetings

- **Why:**
 - Survey
 - Transparency
 - Direct communication /dialogue with stakeholders
- **What:**
 - Different topics/themes based on needs/questionnaires
 - 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'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



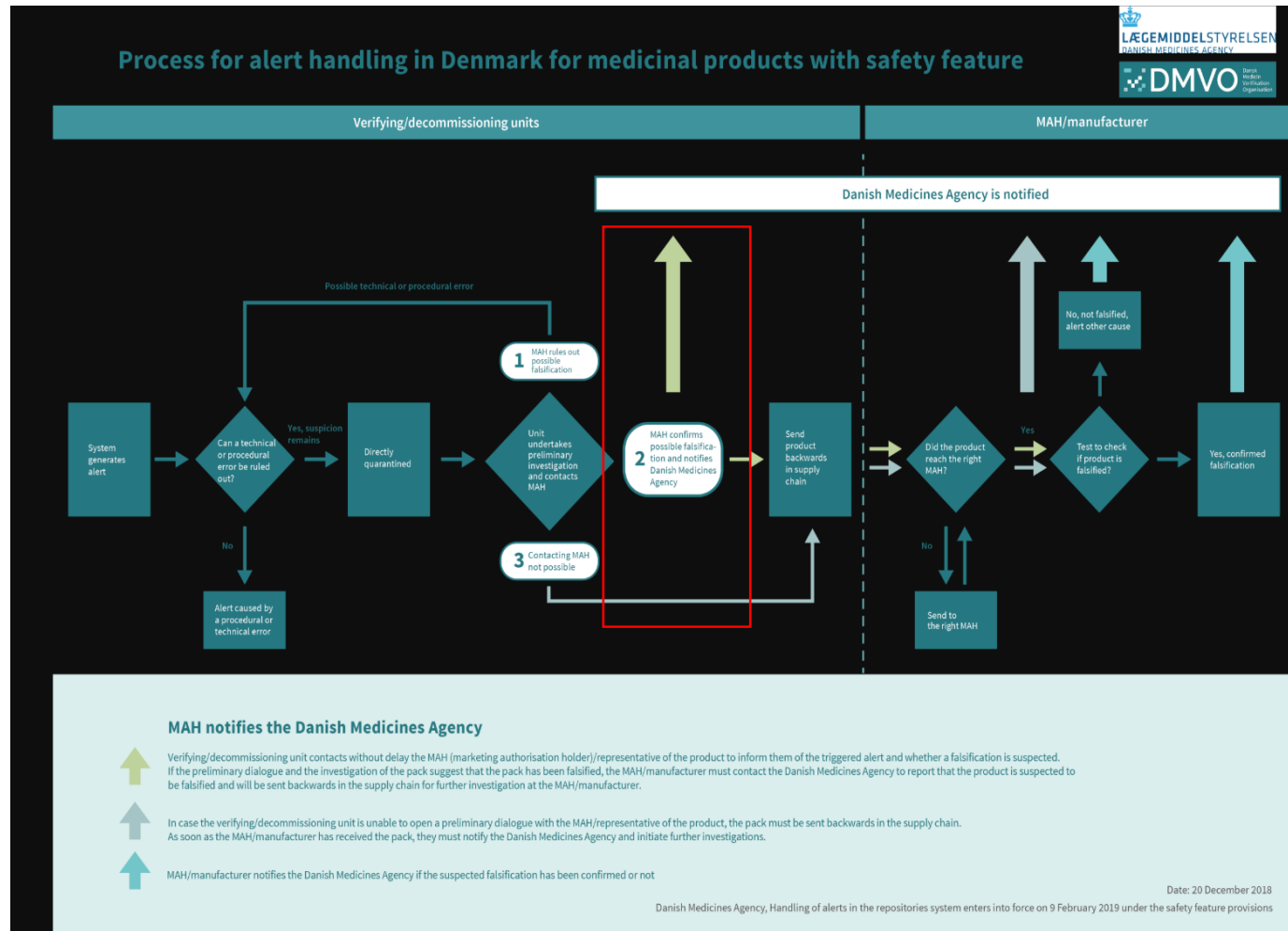
Verifying one pack per batch



- 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

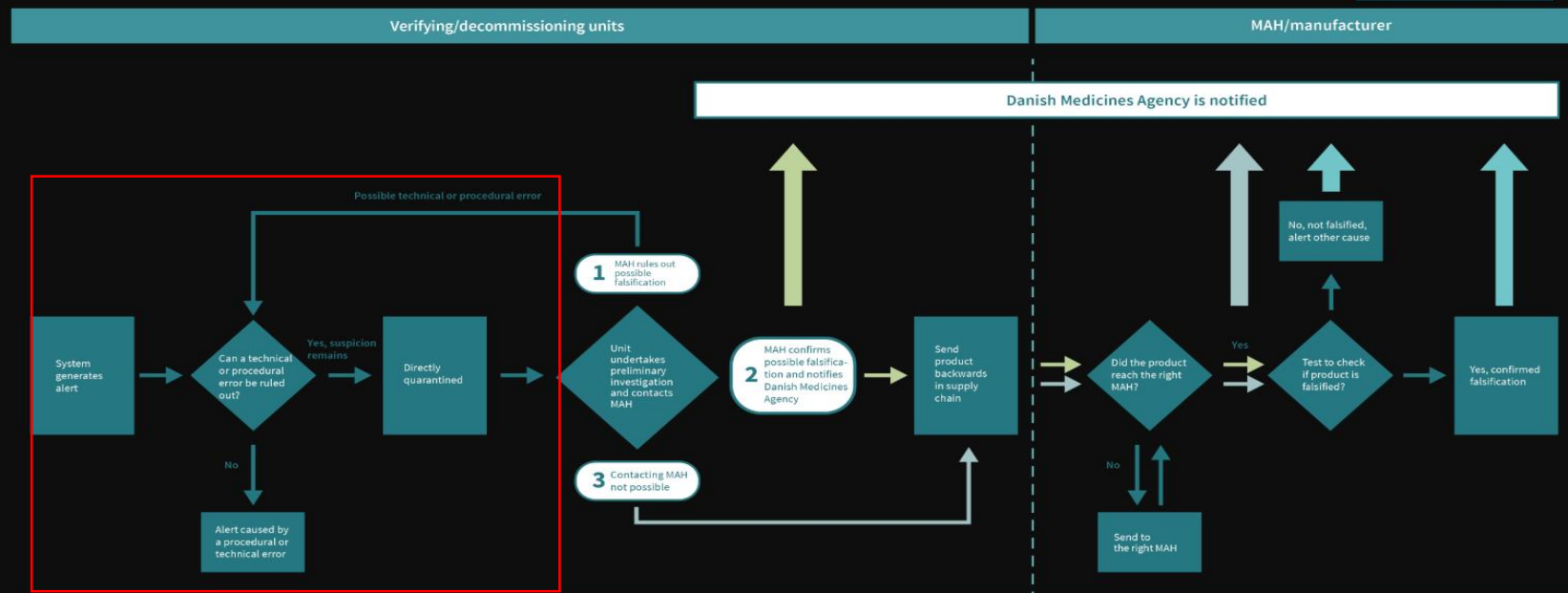
Duty to report to the Danish Medicines Agency

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



DMVO's alert handling procedure for OBP/ MAH

Process for alert handling in Denmark for medicinal products with safety feature



MAH notifies the Danish Medicines Agency



Verifying/decommissioning unit contacts without delay the MAH (marketing authorisation holder)/representative of the product to inform them of the triggered alert and whether a falsification is suspected. If the preliminary dialogue and the investigation of the pack suggest that the pack has been falsified, the MAH/manufacturer must contact the Danish Medicines Agency to report that the product is suspected to be falsified and will be sent backwards in the supply chain for further investigation at the MAH/manufacturer.

In case the verifying/decommissioning unit is unable to open a preliminary dialogue with the MAH/representative of the product, the pack must be sent backwards in the supply chain. As soon as the MAH/manufacturer has received the pack, they must notify the Danish Medicines Agency and initiate further investigations.

MAH/manufacturer notifies the Danish Medicines Agency if the suspected falsification has been confirmed or not

Date: 20 December 2018

Danish Medicines Agency, Handling of alerts in the repositories system enters into force on 9 February 2019 under the safety feature provisions



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” is an automated tool for displaying alert information and performing investigations.

Result

Download list Print list Search:

AlertId	Date	Error code	Product Name	Batch	MAH	Location	End User Status	NMVO Status	MAH Status	Notif.	Resp.
DE-TST-7ZJ-44L-K2H-003	12.3.2020 11:14	A3	Yellow pills	BTC123	World Class Medicines Ltd.	DE-USER-IQE-0001	Open	Open	Resolved		M
DE-TST-7ZJ-44L-K2H-002	12.3.2020 10:51	A2	Orange pills	TEST456	World Class Medicines Ltd.	DE-USER-IQE-0001	Open	Resolved	Open	ME	M
DE-TST-7ZJ-44L-K2H-001	12.3.2020 09:57	A2	Orange pills	TEST456	World Class Medicines Ltd.	DE-USER-IQE-0001	Open	Open	Open		

Resolved

NMVO inspection

SecurPharm
 Hamburger Allee 26-28
60486 Frankfurt am Main
NMVS: Solidsoft Reply NBS

NMVO response:

NMVS Technical error
 NMVS Procedural error
 Other

NMVO actions:

Mark NMVS inspection closed
 Mark resolved
 Apply on a batch level

Inform end user
 Inform MAH
 MAH replied

MAH

Insert comments

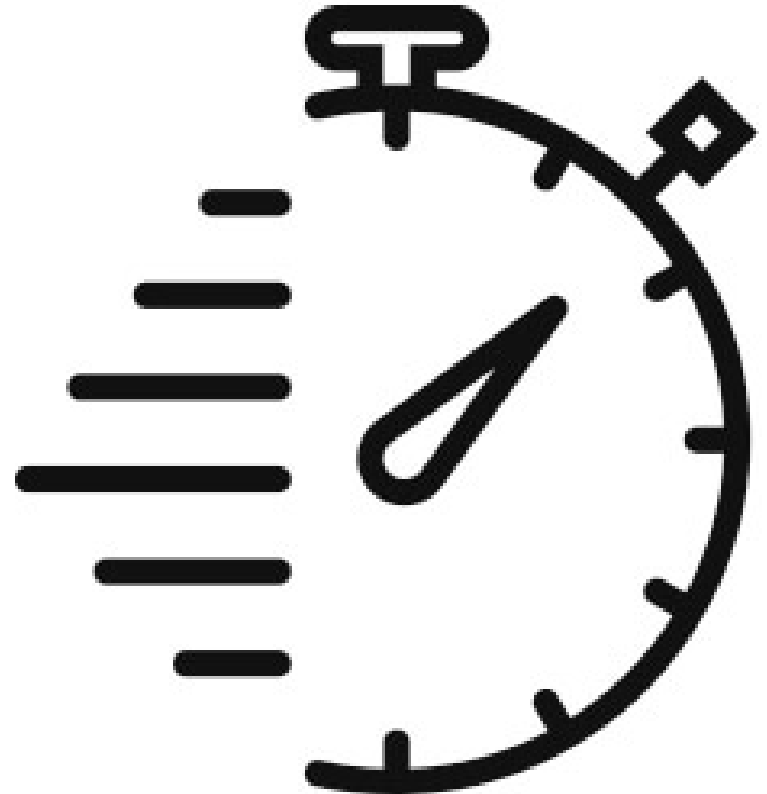
Predefined comments

Save

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!



