DMVO´s alert handling procedure for Marketing Authorisation Holders

Abbreviations

Abbreviation	Explanation
DMVO	Danish Medicines Verification Organisation
NMVS	National Medicines Verification System
EMVS	European Medicines Verification System
OBP	On Boarding Partner
NMVS Alerts	The alert handling system of DMVO

Verifying one pack per batch:
One pack per batch shall be verified by the On Boarding Partner, OBP, before release to the national market with the aim of securing data is correct and correctly uploaded to the European Hub (EMVS). This is done by scanning one pack per batch. If the pack cannot be verified the batch must be contained and data corrected. Past any correction, the batch shall be verified again.
Additionally, DMVO encourages to review the receipt from the European Hub on the distributed data to the National Medicines Verification System (NMVS) to ensure that the batch has been correctly uploaded.

Duty to report:
There is duty to report any findings of medicinal products that are or may be falsified medicinal product packs to the Danish Medicines Agency. For more, pls. see the homepage of the Danish Medicines Agency.

How to investigate an alert?

Step 1

Check if the alert has been triggered due to a technical - or procedural error. The check needs to be done where the alert is triggered.

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 and GTIN number*. The 2D data matrix code should correlate with the readable information printed on the package and data uploaded in the HUB.

Incorrect serial number/ too short or too long:
Is the serial number incorrect? If an alert occurs when verifying a pack per batch, 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

Suspected falsification:

If a technical and procedural error can be excluded, there will be a suspicion of falsified medicine, which must be reported to the NCA; rapidalert@dkma.dk

Emergency lines:

According to the Directive, 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.

Reporting alerts to DMVO:

With the aim of assisting and monitoring the number of alerts, DMVO asks MAH's to send investigations/root causes of alerts to DMVO; info@dmvo.dk

DMVO´s information needs when investigating alerts:

Kindly provide following mandatory information:

1) Alert Id
2) Batch number (LOT/Batch)
3) Product code (PC/GTIN)
4) Expiry date (EXP)
5) Contact person

Optional information:

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

Nordic article numbers are not taken into consideration when investigating.

Expected response time

The expected response time from the first DMVO inquiry is 3 working days. The expected correction time on incorrect data is 3 working days.