

Danish Medicine Verification Organisation

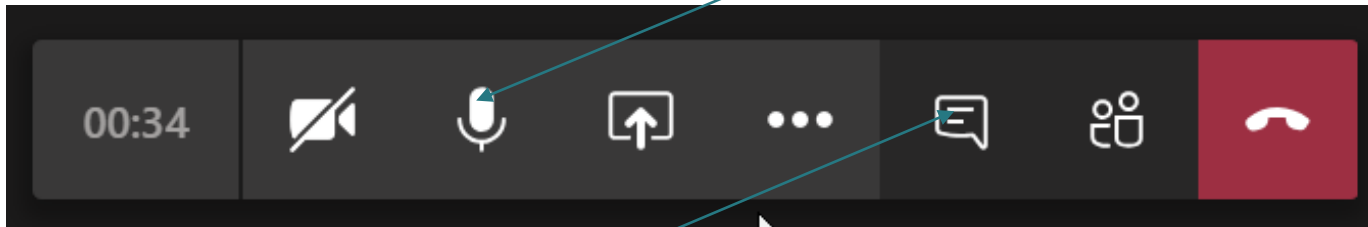
Virtual Meeting 23.06.2020

DMVO's Alert handling Management Tool - NMVS Alerts



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



Alert handling Management Tool - NMVS Alerts

Walk through of the agenda of today's meeting:

- Types of users
- The alert page list
- Access to the alert details page
- Alert details
- DMVO Inspection area
- MAH/OBP Inspection area
- NCA Inspection area
- Action Log
- Signing up/registration



Types of Users in NMVS Alerts - "360"



- **End User**

- Wholesaler
- Pharmacy
- Hospital Pharmacy
- Other persons authorised or entitled to supply medicines to the public

- **Manufacturer**

- OBP
- MAH

- **NMVO**

- **NCA**

The alert page list

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

Alerts Unresolved

01.02.2020 00:00 30.04.2020 23:59 Error Code Alert ID

MAH Product Name Batch ID Location Name Resolved

🔄 ✖

Status

End User

Open

Investigated

NMVO

Open

Investigated

Resolved

MAH

Open

Investigated

Resolved

Results

[Download List](#) [Print List](#)

<input type="checkbox"/>	Alert ID	Date	Error Code	Product Name	Batch ID	MAH	Location Name
<input checked="" type="checkbox"/>	DE-QH0-72J-44L-K2H-003	21.4.2020 09:57	A2	Orange pills	DETEST3	World Class Medicines Ltd.	DE-USER-IQE-0001
<input type="checkbox"/>	DE-QH0-72J-44L-K2H-004	21.4.2020 09:57	A2	Orange pills	DETEST3	World Class Medicines Ltd.	DE-USER-IQE-0001
<input type="checkbox"/>	DE-QH0-72J-44L-K2H-005	21.4.2020 09:57	A2	Orange pills	DETEST3	World Class Medicines Ltd.	DE-USER-IQE-0001
<input type="checkbox"/>	DE-TST-72J-44L-K2H-002	12.3.2020 10:51	A2	Orange pills	TEST456	World Class Medicines Ltd.	DE-USER-IQE-0001
<input type="checkbox"/>	DE-TST-72J-44L-K2H-001	12.3.2020 09:57	A2	Orange pills	TEST456	World Class Medicines Ltd.	DE-USER-IQE-0001

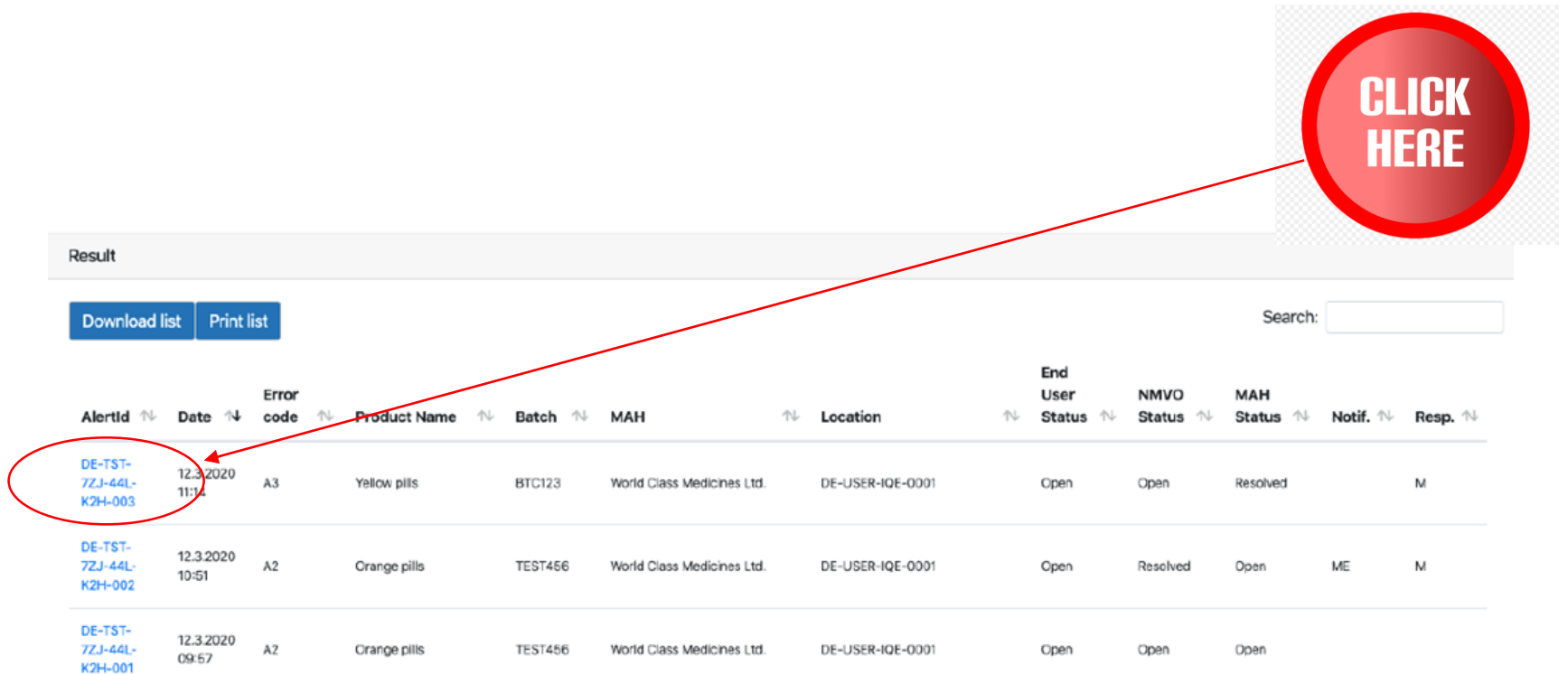
Showing 1 to 5 of 5 entries

Search:

End User Status	NMVO Status	MAH Status	Notif.	Resp.
Open	Resolved	Investigated		M
Open	Resolved	Investigated		M
Open	Resolved	Investigated	ME	M
Open	Resolved	Investigated	E	ME

Previous 1 Next

Access to the Alert details page - "zoom in on alerts"



The screenshot shows a web interface for alert management. At the top right, a red circular callout bubble with the text "CLICK HERE" is connected by a red arrow to the first alert ID in the table below. The table has columns for Alertid, Date, Error code, Product Name, Batch, MAH, Location, End User Status, NMVO Status, MAH Status, Notif., and Resp. The first row is circled in red, and its alert ID is also circled in red.

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		

- Click on the blue alert ID to "zoom" on the alert and have detailed information on the alert(s)

AND EACH FEATURE
NEEDS TO HAVE
WHAT WE CALL A
"USER STORY."



Alert Details


[← Back to List View](#)

Alert Details



Alert ID	DE-QHO-7ZJ-44L-K2H-001	Error Code	A7	Market	Germany
Date/Time	21. 04. 2020 11:57	Error Message	Pack Already in Requested State	Source Market	DE
Product Code	90642600000001	Provided Batch	DETEST1	Provided Expiry	230300
Serial Number	01234567890	Stored Batch		Stored Expiry	
Manual Entry	False	Location ID	DE-USER-IQE-0001		
Attempted Operation	SUPPLIED	Business Process	National System Single Pack API		

End User Inspection Area

Open 

End User Inspection

🕒 16. 06. 2020 10:21
👤 Demo Pharmacy DK
📍 Demo alley 1, 1111 Demoville
IT Vendor: NMVS Connect

☎ +123456789
✉ enduser+dk@nmvs-alerts.com

NMVS Response



🖨️

Scanner Output String
External System API Response
The expiry date mismatches the recorded expiry date. An alert has been raised.
Pack State:

Level 1 Investigation


- Technical Error
- Procedural Error
- Pack Returned
- Other
- Mark Investigated
- Inform NMVO

Insert comments here...





  **Save**

- Address and contact information of the End User is not visible to OBP/MAHs.

DMVO Inspection Area

Investigated 

NMVO Inspection

 SecurPharm  +49 69 979 919 121
 Hamburger Allee 26-28, 60486 Frankfurt am Main  nmvo-iqe@nmvs-alerts.com
NMVS: Solidsoft Reply NBS

NMVO Response:

NMVS Technical Error
 NMVS Procedural Error
 Other

NMVO Actions:


Mark Investigated
 Mark Resolved
 Apply on a Batch Level

Inform end user
 Inform MAH
 MAH Replied

MAH


Batch ID Unknown

Pre-Defined Comments





 **Save**

- Inspection details can be viewed by any stakeholder for a specific alert
- Information can be added and modified only by selecting the checkboxes, attaching documents or including comment

MAH/OBP Inspection Area


Resolved 

MAH Inspection

 World Class Medicines Ltd. Germany	 +123456789  obp-iqe@nmvs-alerts.com	Pack Data: PC: 90642600000001 SN: 01234567890 LOT: DETEST1 EXP: 230300 <input type="checkbox"/> Ask for Pack Photo <input type="checkbox"/> Require Pack Return	Product name: Yellow pills Wholesaler: World Class Wholesaler Ltd., 123 Demo street, Demo city 1234	
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NOT COUNTERFEIT		SUSPECTED COUNTERFEIT		<input checked="" type="checkbox"/> Mark Investigated <input checked="" type="checkbox"/> Inform NMVO <input checked="" type="checkbox"/> Mark Resolved <input type="checkbox"/> Apply on a Batch Level <input type="text" value="Suspected Reason"/>
MAH Reasons: <input type="checkbox"/> Master Data Not Uploaded <input checked="" type="checkbox"/> Pack Data Not Uploaded <input type="checkbox"/> Incorrect Data <input type="checkbox"/> Other (add comment)	Action Taken: <input type="checkbox"/> Master Data Uploaded <input checked="" type="checkbox"/> Pack Data (Re)uploaded <input type="checkbox"/> Pack Data (Re)uploaded for BATCH	Findings: <input type="checkbox"/> UID Not Found in MAH System <input type="checkbox"/> UID Decommissioned in MAH System <input type="checkbox"/> The Pack Looks Suspicious on the Received Photo	Conclusions: <input type="checkbox"/> Confirmed Counterfeit <input checked="" type="checkbox"/> Not Counterfeit	



Pack data not uploaded due to EMVS technical issue. Pack data re-uploaded. Not counterfeit. Investigation closed.



 **Save**

Inform NCA

NCA Inspection Area

NCA Involvement informed 

 NCA DE  0221 794790

 Test street 003 , 1 Berlin  nca@nmvs-alerts.com

NCA Involved in Inspection

Inform NMVO

Inform MAH

Inform end user

Insert comments here...

- When “Inform NCA” is clicked, the color of the flag of NCA involvement changes to yellow. Only the NCA can add further information to this section.
- 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



Action Log per alert

- All actions taken within the Alert Details page are logged for the specific alert and can be viewed or printed

Action log				
Seq.	Date/time	Actor/Level	Action	Attachment
1	13. 03. 2020 10:27:21	Manufacturer	Inform NCA	
2	13. 03. 2020 10:29:05	NMVO	Suspected reason select: MAH	
3	13. 03. 2020 10:29:05	NMVO	Added: Mark NVMS inspection closed,Mark resolved.	
4	13. 03. 2020 10:29:05	NMVO	Inform MAH	
5	13. 03. 2020 10:29:06	NMVO	Inform end user	
6	13. 03. 2020 10:29:06	NMVO	MAH replied	

 Print alert

Demo

■ Live demo

The screenshot displays a software interface for managing alerts. At the top, there is a header for 'Alert Details' with a search icon and '100 jobs' indicator. Below this is a table with the following data:

Alert ID	Alert Name	Alert Status	Alert Message	Alert Level
100-1000-1000	100-1000-1000	Open	100-1000-1000	High

The main content area is divided into several sections:

- Bad User Investigation:** Includes a 'Bad User Investigation' section with a 'Bad User Investigation' button and a 'Bad User Investigation' text area. It also has a 'Bad User Investigation' section with a 'Bad User Investigation' button and a 'Bad User Investigation' text area.
- Bad User Investigation:** Includes a 'Bad User Investigation' section with a 'Bad User Investigation' button and a 'Bad User Investigation' text area. It also has a 'Bad User Investigation' section with a 'Bad User Investigation' button and a 'Bad User Investigation' text area.
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At the bottom, there is an 'Action Log' section with a table:

Date	Alert Name	Action Label	Action	Attachment
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Signing up for NMVS Alerts



Kindly send name and email 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

Question time!



