


<b>nmvs</b> alerts	NMVS Alerts – User manual	
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# NMVS Alerts User manual



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## 1. Overview

**NMVS Alerts** offers a modern, effective and highly automated tool for displaying alert information and performing appropriate inspection measures that can be used in all participating countries. Designed as a **collaboration platform** for all involved Target Groups, i.e. NMVOs, MAHs, End Users and NCAs. NMVS Alerts supports the needed escalation and de-escalation procedures.

In addition to the alerts database, stakeholders can ask for and exchange helpful information such as documents, images or remarks. Log information are tracked through the whole process. NMVS Alerts is a very easy to use and cost efficient, web-based application.

## 2. Access to NMVS Alerts

To get access to NMVS alerts portal, you have to be on-boarded by the NMVO in your country. Please contact your NMVO for instructions how to get you registered. After you have successfully completed the registration process, you can log in with your email address and password at: <https://app.nmvs-alerts.com>

Depending on your NMVO's policy, you may also get access to certain alerts without being registered. The NMVO can send you a notification email with a unique link, which grants you one-time access to a particular alert. The link will expire after a certain time period, or once you have saved any changes to the alert in question.

## 3. Alerts list view


When you log in to NMVS Alerts, you will land on the List Alerts page. This is the overview page of the application, where all visible alerts can be screened. The user gets access only to his own alerts, or alerts for which he has permission granted from other users.


### 3.1 Alert Filter criteria


The filter options help you to see only what is relevant for you. You can set one or more values at the same time to easily find the alerts you're looking for. Click the refresh button to apply the settings, or the clear button to clear all filter criteria.



#### List Alerts

Filter criteria
 Open







Apply filter
Clear filter

You can choose between the following options:

- Start and end date
- Error code – choose between the common alert codes (A2, A3, A7...)
- MAH – Search for one or more MAHs – multiple can be selected.
- Product name – choose a product by name.
- Batch – Type a batch ID. Only exact matches will be shown
- Location / Country – Search for one or more locations – multiple can be selected. For MAH users, this attribute is replaced by the Country attribute.
- Status – choose one of the common alert statuses, as described in chapter 5.
- Alert ID – if you're looking for a particular alert ID, type it here.

## 3.2 Sorting of results

After pressing the Refresh Button, the results are displayed at the bottom of the page. You can use the up or down arrow to sort the results accordingly.

AlertId	Date	Error code	Product Name	Batch	MAH	Location	End User Status	NMVO Status	MAH Status	Notif.	Resp.
<a href="#">SI-1V4-456-789-MAN</a>	5.11.2019 13:53	A52	White powder		World class medicines ltd	Pharmacy 01	Open	Open	Open		
<a href="#">SI-1V4-456-789-MX3</a>	4.11.2019 09:14	A3	Super strong	Test-P3-MX	World class medicines ltd	Test Location	Open	Closed	Open		
<a href="#">SI-1V4-456-789-MX1</a>	4.11.2019 09:13	A3	Super strong	Test-P3-MX	World class medicines ltd	Pharmacy 01	Open	Closed	Open	E	E

## 3.3 Search in result list

In the Search field you can enter an arbitrary string for a free text search. The entered string will be searched through all data attributes of the alerts in the current range.

## 3.4 Download and Print


You can download the result list in an .xlsx file or print it out on your printer devices.

## 4. Alert Details Page

To get all available information of a specific alert, you click on the blue marked Alert-Id in the result list. You will then enter the "Alert Details Page". This page is designed as a collaboration platform and contains a complete description of the alert, all inputs, remarks, requests from the involved stakeholders as well as detailed alert status information.

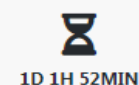
### 4.1 Alert Details

On top of the page you will recognize the details of the alert under investigation. Most of the fields do not need any explanation.

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#### Alert details

<b>AlertId</b>	SI-OVP-8U5-B8N-MJE	<b>Error code</b>	A3	<b>Market</b>	Slovenia
<b>Date/Time</b>	29. 05. 2019 07:46	<b>Error message</b>	Serial Number not found.	<b>Source market</b>	Si
<b>Product code</b>	93837000095609	<b>Provided batch</b>	1041939	<b>Provided expiry</b>	231231
<b>Serial number</b>	CCf8T3Z9EC	<b>Stored batch</b>	1041939z	<b>Stored expiry</b>	231200
<b>Manual entry</b>	False	<b>Location ID</b>	BGb8fc92-f9f4-42a8-8f64-36bcd5f2ba1		
<b>Attempted operation</b>	SUPPLIED	<b>Business process</b>	National System Single Pack API		



The hourglass on the right displays the time passed since the alert has been created in the NMVS.

The “Provided Batch” contains the batch number of the scanned barcode, whereas the “Stored Batch” contains the batch number, which is stored in the national system, if it exists.

The “Provided expiry” displays the expiry date in the scanned barcode, whereas “Stored expiry” means the expiry date, which is stored in the national system, if it exists.

## 4.2 End user inspection details

The End user inspection details is the area where end users can provide information about the alert. This area is also available for editing to the NMVO, since it’s possible that the end user communicates with the NMVO by another means of communication. MAHs or NCAs can read but not modify the level 1 inspection details. The address information of the End user is not visible for MAHs.

#### Level 1 inspection details

**End user**

29. 05. 2019 07:46

Test1

Test road 111, 1000 Ljubljana

It vendor:NMVS Connect

**NMVS response**

Scanner output string


NMVS response message

Pack state:

**Level 1 investigation**

Technical error  
 Procedural error  
 Pack returned  
 Other  
 Mark level 1 closed


Insert comments



End users can provide information by clicking the checkboxes in the right part of this section, insert comments, attach documents or take a picture of the pack using a webcam (only End user). Confirming with the Save button adds this information to the information log (see section 5.6).

The end user should:

- Mark the “Technical error” checkbox, when they can confirm the root cause of the alert was a technical issue on their side, i.e. problems with scanning equipment or client software.



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- Mark the “Procedural error” checkbox, when they can confirm the root cause of the alert was a procedural error on their side, i.e. scanning the same pack multiple times, attempting incorrect transactions etc.
- Mark the “Pack returned” checkbox, when they have sent the pack back to the supplier.
- Mark the “Other” checkbox and submitting a message in the Comment text box, when they want to tell the other stakeholders something else, i.e. stating that they are certain the issue was not caused at their side.
- Mark the “Level 1 closed” checkbox, when they have finished the investigation on their side with either result.

### 4.3 NMVO inspection details

#### Level 2 inspection details

**NMVO inspection**

 Test NMVO       123 45 678

 Prešernov trg 1, 1231 Ljubljana       info@origimed.eu

**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

Closed 


Insert comments

Predefined comment ▼

Inform end user

Inform MAH

MAH replied

 **Save**

Information can be added and modified by NMVOs only.

The NMVO should:

- Mark the NMVS Technical error checkbox, when the alert was caused by a technical error on the national system or the European HUB
- Mark the NMVO Procedural error checkbox when the alert was caused by a procedural error in the NMVO.
- Mark the NMVS Inspection closed checkbox when they have finished investigation on their side and have asked other stakeholders to take over investigation of the alert in question.
- Mark the “Resolved” checkbox, when a root cause of an alert has been identified and confirmed by any of the stakeholders. The alert status is changed to Resolved.
- Use the “Inform End user” and “Inform MAH” options to send a notification email to the respective stakeholder.

## 4.4 MAH inspection

Open

**MAH inspection**

World class medicines Ltd  
Slovenia

01 234 567 890

info@wcm.com

**Pack data:**

PC: 95413800000001  
SN: 01234567896  
LOT: Test-P3-MX  
EXP: 230300

Ask for pack photo

Required pack return

**Product name:**

Super strong medicine

**Wholesaler:**

Supreme wholesaling Ltd,  
403 Forbidden Street, 0,  
Nowhere, 1221

150 x 150

---

NOT COUNTERFEIT

**MAH reasons:**

Master data not uploaded

Pack data not uploaded

Incorrect data

Other (add comment)

SUSPECTED COUNTERFEIT

**Action taken:**

Master data uploaded

Pack data (re)uploaded

Pack data (re)uploaded for BATCH

Resolve alert

Apply on a batch level

**Findings:**

UID not found in MAH system

UID decommissioned in MAH system

The pack looks suspicious on the received photo

**Conclusions:**

Confirmed counterfeit

Not counterfeit

Insert comments

Mark closed

Inform NMVO

Information can be added or modified by MAHs only.

The MAH should:

- Mark the “Closed” checkbox, when they have finished investigation but weren’t able to confirm the root cause of the alert.
- Mark the “Resolve alert” checkbox, when they were able to determine the root cause of the alert and apply any possible corrective actions. The alert status is changed to Resolved.
- Use the “Ask for pack photo” checkbox when a photo of the pack is required. This action will send a notification email to the end user, requesting them to upload a photo of the pack.
- Use the “Request return of pack” checkbox when the pack should be returned for examination. This action will send a notification email to the end user, requesting them to return the pack to the MAH.
- Use the “Inform NMVO” checkbox when they want to notify the NMVO about anything. This action will send a notification email to the NMVO.

## 4.5 Inform NCA



The blue button “Inform NCA” can be used by any user of NMVS Alerts. This action will send a notification email to the NCA, which was on boarded by the NMVO.



## 4.6 NCA involvement


When the blue button “Inform NCA” was pushed, the colour of the flag of the Level 3 inspection details changes to yellow. Again, only the NCA can add further information to this part.

### Level 3 inspection details

**NCA involvement**

 JAZMP  
 Test road 156, 1000 Ljubljana

 01 123 45 56  
 info@origimed.eu

Informed 

NCA involved in inspection

Insert comments

[Save](#)

## 4.7 Action log

All inputs to the Alerts Details Page are logged and can be viewed or printed at the bottom of the page.

**Action log**

Seq.	Date/time	Actor/Level	Action	Attachment
1	30. 05. 2019 10:49:54	NMVO	Inform NCA	
2	30. 05. 2019 10:57:09	NMVO	Added: Pack returned,Other.	
3	30. 05. 2019 10:57:15	NMVO	Added: Mark resolved.	

[Print alert](#)

## 5. Alert status

### 5.1 Status on the end user level (Level 1)

Status on the end user level can be changed by the end user or the NMVO. The NMVO may change status on this level if communication with the end user took place via another means of communication (not through NMVS Alerts).

**Open** – This is the default status. It means that the end user has not yet investigated the alert in any way

**Closed** – This status means that the end user has investigated the root cause of alert and updated the necessary information accordingly.


### 5.2 Status on the NMVO level

Status on the NMVO level can only be modified by the NMVO.

**Open** – This is the default status. It indicates that the alert hasn't been investigated by the NMVO yet.

**Closed** – The NMVO has investigated the alert and has informed the other relevant stakeholders (End user or MAH) to take further actions. The root cause is not identified yet.



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**Resolved** – The NMVO has investigated the alert and has positively identified the root cause of the alert, which was a technical or procedural error with one of the stakeholders. The end user may attempt to dispense the medicine again, if applicable.

### 5.3 Status on the MAH level

Status on the MAH level can only be modified by the MAH.

**Open** – This is the default status. It indicates that the alert hasn't been investigated by the MAH yet.

**Closed** – The MAH has investigated the alert, but wasn't able to confirm the root cause. The MAH has informed other stakeholders (End user or NMVO) to take further actions.

**Resolved** – The MAH has investigated the alert and has positively identified the root cause of the alert, which was a technical or procedural error on the MAH side. The MAH has also taken relevant corrective actions, so the end user may attempt to dispense the pack again, if applicable.

## 6. Settings

### 6.1 Account Settings

The account settings page allows users to change the following information: name, surname, display info email, display info phone, and password. The password must meet minimum complexity requirements (at least 8 characters and 3 of the 4 character types – capital letters, small letters, numbers, special characters).