



WEBINAR ONLINE



Falsified Medicines Directive:
Alert management and quarantine
rules in BELUX



AGENDA

- Why only now a FULL EU FMD implementation?
- EMVO Best practice in Alert management
- Principles
- Role of each stakeholder in alert management
- Alert management procedure from 9 February 2024
- Quarantine rules from February 9, 2024
- How to handle an alert on the NMVS Alerts platform?



Why only now a Full EU FMD Implementation?

Because the target set by FAGG/AFMPS in 2019 to switch to a Full FMD has only recently been reached, namely an alert rate of 0.05% on the total of transactions.



Ozempic counterfeit discovered by the EMVS





EMVO best practice in Alert Management

<https://emvo-medicines.eu/new/wp-content/uploads/Best-Practice-on-Alert-Handling.docx.pdf>

The purpose of this document is to propose best practices for handling alerts generated in the EMVS when the system is in a stable state and alerts due to technical, or procedural errors have been minimized, so that the alert rate is close to 0.05% of the total number of scans or lower.

It contains decision trees for the examination of alerts and the time at which the competent authority should be notified. It also defines the role of end-users, MAHs, NMVOs and EMVOs and describes the communication channels between them, including alert management systems where they are present.

Principles

Quarantine products until alert is resolved

Data protection and anonymity.

Only FAGG/AFMPS and BeMVO know the identity of the pharmacist, hospital or wholesaler

Simplifying, facilitating and accelerating communication between the different parties

Striving for uniformity in the handling of alerts throughout Europe

Responsibilities of the MAH under the FMD

- **Correctly upload packaging data to the EU Hub before products are placed on the market**
- Avoid putting decommissioned products on the market.
- Monitor the alerts on your products
- Document the investigation of the alerts in the AMS platform
- Respond to questions and requests from BeMVO, FAGG/AFMPS, pharmacists and wholesalers in the AMS platform
- Solve technical problems as quickly as possible (upload data)
- Confirmation of counterfeits (request for the relevant packaging)



Responsibilities of the wholesaler under the FMD

- **Verify returns and remove already decommissioned products from the supply chain**
- Avoid double decommissioning of:
 - Vaccines
 - Products for destruction
 - Free Samples
- Be vigilant with every alert
- Quarantine a product until a counterfeit is ruled out
- Document the alert investigation in the AMS platform
- Respond to questions and requests from BeMVO, FAGG/AFMPS and MAH in the AMS platform
- Resolve technical issues as soon as possible.



Responsibilities of pharmacists under the FMD

- **Be vigilant with every alert**
- Quarantine a product until a counterfeit is ruled out
- Document the alert investigation in the AMS platform
- Respond to questions and requests from BeMVO, FAGG/AFMPS and MAH in the AMS platform
- Prevent double decommissioning
- Resolve technical issues as soon as possible.





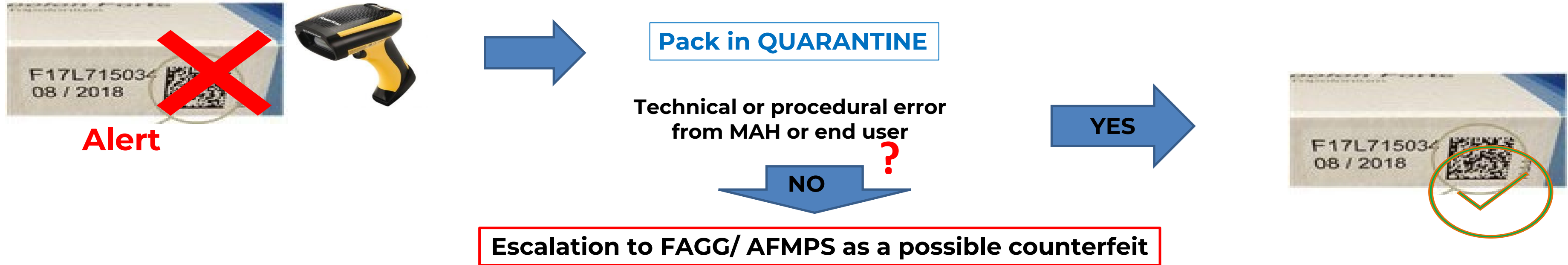
Responsibilities of BeMVO in alert management

- Follow up on alerts that remain unaddressed after 2 and 4 days (e-mail)
- Assist in the investigation of an alert by means of "Pack full audit trail"
- Closing alerts that have been adequately handled and where falsification has been excluded.
- Facilitating communication between the various stakeholders

Responsibilities of FAGG/AFMPS in alert management

- Confirmation of counterfeits (request for the packaging in question)
- National and international communication in case of counterfeits
- Monitoring: FAGG/ AFMPS has access to all alerts via the alert management system, not just those that have the status "escalated".
- Granting and communicating derogations
- Supervise compliance of pharmacists, wholesalers and MAH's with the EU FMD regulations (audit, inspections)

Alert management procedure - 2024



In case of alert :

1. Packaging is kept separate
 2. Immediate investigation by end-user and MAH, verify whether the alert has been caused by:
 - a "Technical error" (scanner/SW problem, failed data upload, etc.)
- or
- a 'Procedure error' (scan the same packaging several times, scan free samples, data upload not done, ...)

3. Possible exchange of information between end-user and authorization holder to 'resolve' the alert (e.g. end-user provides a photo of the package to MAH, ...)
4. If no progress has been made within 2 days or if no cause has been found for the alert, BeMVO will contact the end user and the license holder to speed up the investigation
5. If no solution has been found after 5 days or if no technical or procedural error has been found by the end user/MAH, the system will automatically escalate to NCA.

When can the end user deliver a package after an alert has been triggered?

- The end-user states: "Cause on my end" + "Technical error" or "Procedure error", and indicates in the comment section how the problem was resolved:
 - The packaging was correctly decommissioned after the alert was triggered
 - Decommissioning after a successful “undo dispense”
 - Successful re-scan after technical problem
 - Successful manual entry of GTIN, SN, batch number and expiry date after technical problem
- **Successful re-scan after the batch has been properly downloaded by the MAH**
- **FAGG/AFMPS closes the alert and adds in the comments that the packaging can be delivered = derogation**

When can an alert be closed by the MAH?

- MAH caused the alert in the EU-HUB and solved the alert.
- End user triggered the alert in the NMVS because MAH did not upload the batch data (cause of the alert at MAH side) , MAH can close the alert after batch was correctly uploaded
- BeMVO closed the alert
- FAGG closed the alert

How to handle an alert on the NMVS Alerts platform?



Registration E-mail



**EU FMD - European Falsified Medicines Directive
Alert Management**

Beste ,
In het kader van de Full FMD implementatie vanaf 9 februari 2024 in België en Luxemburg, werd uw account bij NMVS Alerts geactiveerd.

Voltooi uw registratie door op onderstaande link te klikken:

[Klik hier!](#)

Gelieve contact op te nemen met ons support-team bij vragen of problemen:

support@bemvo.be

BeMVO - LMVO team

BEMVO - LMVO

www.bemvo.be

www.lmvo.lu

support@bemvo.be

NMVS Alerts Portal

Registration E-mail



EU FMD - European Falsified Medicines Directive
Alert Management

Beste,
Uw unieke beveiligingscode is:

123456

Voer deze code in op de login pagina om verder te gaan.

Bij technische problemen, gelieve contact op te nemen via

support@bemvo.be

BeMVO - LMVO team

BEMVO - LMVO

www.bemvo.be

www.lmvo.lu

support@bemvo.be

NMVS Alerts Portal

Notification e-mail



EU FMD - European Falsified Medicines Directive
Alert Management

Beste,
Uw NMVO heeft nieuwe informatie toegevoegd aan alert
SOL-14125-1251251-25125

Het bericht van uw NMVO:
Check your scanner

Klik op volgende link om de alert details weer te
geven en het alert te behandelen.

[Click here!](#)

Door op de link te klikken, gaat
u akkoord met de [Terms & Conditions](#).

Voor een overzicht van al uw alerts, kan u zich inloggen via volgende link:
[NMVS Alerts portal](#).

Gelieve contact op te nemen met ons support-team bij vragen of problemen:

support@bemvo.be

BeMVO - LMVO team

Registration E-mail (English translation)

1st mail

Dear

As part of the Full FMD implementation from 9 February 2024 in Belgium and Luxembourg, your account with NMVS Alerts has been activated.

Please complete your registration by clicking on the link below:
click here

Please contact our support team with any questions or problems:
support@bemvo.be

2nd mail

Dear

your unique security code is: 123456

please enter this code on the login page to continue. In case of technical problems, please contact us at
support@bemvo.be

3rd mail

Dear

your NMVO has added new information to alert : SOL-14125-125125-25125

The message from your NMVO: Check your scanner

please click on the following link to view the alert details and handle the alert: click here
by clicking on the link, you agree to the Terms & Conditions.

for an overview of all your alerts, please log in via the following link: NMVS Alerts portal

Please contact our support team with any questions or problems:
support@bemvo.be

NMVS Alert platform

Alerts filteren

Verberg Gesloten Alleen bijgewerkt Alleen met ster

Een opgeslagen filter gebruiken

Periode

28.11.2023 - 30.11.2023

Alert ID

MAH

Select

Batch-ID

Foutcode

Select

Serienummer

Opgeslagen batch ID

Handmatige invoer

Beide True False

Last week
Last month
Last 3 months

2023 November

Sun	Mon	Tue	Wed	Thu	Fri	Sat
29	30	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	1	2
3	4	5	6	7	8	9

2023 November

Sun	Mon	Tue	Wed
26	27	28	29
3	4	5	6
10	11	12	13
17	18	19	20
24	25	26	27
31	1	2	3

Select

- Eindgebruiker
- Geopend
- Onderzocht
- NMVO
- Geopend
- In onderzoek
- Geëscaleerd

Bulk-acties

Zoek meldingen op naam, ID en meer...



<input type="checkbox"/> Alert ID	Datum (UTC)	Retour Code	Productcode	Productnaam	Batch-ID	MAH	Serienummer	Naam van de lo...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> BE-5b86051f-21ae-49ed-a	30.11.2023 09:34	NMVS_NC_PC_02	15412345678905	15412345678905	TOL123		REZ50C00	Testuser01 WHS-L	0	0	0	0

BE-5b86051f-21ae-49ed-ab5d-69adc4f19a9e Onopgelost voor 1d 1h 21Min

☆ 🖨️ 📄 Gerelateerde alerts zoeken

Inspectie Actie Log Contactgegevens

🔗 Eindgebruiker Testuser HOSP-BE

Geopend 0



Niveau 1 Onderzoek

Technische fout

Procedurefout

Verpakking geretourneerd

Andere

Acties

Informeer NMVO

Status wijzigen

Geopend (actief)

Onderzocht

Status van het onderzoek

▼

- Onderzoek in behandeling
- Oorzaak aan mijn kant
- Oorzaak niet aan mijn kant



🔗 Bewaren


Alert Details	
Foutcode A7	Foutmelding NMVS_NC_PCK_19 Property is already set on pack.
Datum 29.11.2023	Tijd 13:34
Productnaam -	Productcode 15412345678905
Serienummer REZ50C50	Groothandelaars -
Markt Belgium	Bron Markt BE
Geleverde batch TOL123	Opgeslagen batch -
Mits vervaldatum 240930	Opgeslagen vervaldatum -
Handmatige invoer False	Locatie ID NMVO2/NAMSBE-H
Poging tot bewerking SUPPLIED	Bedrijfsproces 120
PLU-locatie-ID -	PLU Tijdstempel
PLU-markt -	Retour Code NMVS_NC_PCK_19

BE-5b86051f-21ae-49ed-ab5d-69adc4f19a9e Onopgelost voor 1d 1h 21Min

Alert Details

Foutcode A7	Foutmelding NMVS_NC_PCK_19 Property is already set on pack.
Datum 29.11.2023	Tijd 13:34
Productnaam -	Productcode 15412345678905
Serienummer REZ50C50	Groothandelaars -
Markt Belgium	Bron Markt BE
Geleverde batch TOL123	Opgeslagen batch -
Mits vervaldatum 240930	Opgeslagen vervaldatum -
Handmatige invoer False	Locatie ID NMVO2/NAMSBE-H
Poging tot bewerking SUPPLIED	Bedrijfsproces 120
PLU-locatie-ID -	PLU Tijdstempel
PLU-markt -	Retour Code NMVS_NC_PCK_19

BE-5b86051f-21ae-49ed-ab5d-69adcee19a9e Onopgelost voor 0d 5h 28Min

   Gerelateerde alerts zoeken >

Alert Details

Foutcode A3	Foutmelding NMVS_NC_PC_02 Serialnumber unknown.
Datum 30.11.2023	Tijd 09:34
Productnaam -	Productcode 15412345678905
Serienummer REZ50C00	Groothandelaars -
Markt Belgium	Bron Markt BE
Geleverde batch TOL123	Opgeslagen batch -
Mits vervaldatum 240930	Opgeslagen vervaldatum -
Handmatige invoer False	Locatie ID NMV05/NAMSLU-W
Poging tot bewerking SUPPLIED	Bedrijfsproces 120
Retour Code NMVS_NC_PC_02	

Inspectie Actie Log Contactgegevens

 Eindgebruiker Testuser01 WHS-LUX

Geopend 0



Niveau 1 Onderzoek

Technische fout Procedurefout Verpakking geretourneerd Andere

Acties

Informeer NMVO

Status wijzigen

Geopend (actief) Onderzocht


Status van het onderzoek


Commentaar

Voeg hier opmerkingen in...

5D30BD6F-1172-401D-A.jpeg



 Bewaren

NMVO  BeMVO Wordt onderzocht ✕

Antwoord

Technische fout NMVS NMVS Procedurefout Reason unidentified Andere

NMVO Acties Toepassen op batchniveau

Informeer de eindgebruiker Informeer MAH Informeer de NCA MAH antwoordde

Oorsprong AMS HUB Reden Status van het onderzoek

Status wijzigen



Geopend (actief) Wordt onderzocht Gesloten Geëscaleerd

Commentaar Relevant to End user MAH Add external link

Le numéro de série est-il le même que celui qui figure sur l'emballage ?

[PDR openen](#)

[Bewaren](#)

 MAH Geopend 0 

Bevindingen

<input type="checkbox"/> Verpakkingsgegevens niet opgeladen	<input type="checkbox"/> Bevestigde vervalsing	<input type="checkbox"/> UID niet gevonden in MAH-systeem
<input type="checkbox"/> Geen vervalsing	<input type="checkbox"/> Verpakking gedecommissioneerd in MAH-systeem	<input type="checkbox"/> Anders (voeg een reactie toe)

ACTIES Toepassen op batchniveau

<input type="checkbox"/> Vraag om een foto van de verpakking	<input type="checkbox"/> Retourzending van verpakking eisen	<input type="checkbox"/> Informeer NMVO
<input type="checkbox"/> Informeer de eindgebruiker		

Oorsprong: AMS HUB Reden: Status van het onderzoek:

Status wijzigen

Geopend (active) Wordt onderzocht Gesloten Geëscaleerd


Commentaar

Voeg hier opmerkingen in...

Action log

This section contains an overview of all the information entered by all parties regarding the alert. At the bottom of the page, you will find a summary of all the changes made to the details of the alert, in reverse chronological order.

Actie Log

- | | | |
|--|--|--|
| 2 |  NMVO (*M) |  30.11.2023 15:16 |
| Status gewijzigd van Geopend naar Wordt onderzocht | | |
| 1 |  NMVO (*M) |  30.11.2023 15:16 |
| Commentaar: Komen de gegevens die u invoerde overeen met de FMD-informatie op de verpakking? | | |



Options to connect MAHs to the Belgian NAMS



Connecting MAHs in Belgium to NAMS

(Option 1)



Onboarding to NAMS by BeMVO

- ✓ Login to Belgian NAMS via Credentials
- ✓ All Belgian alerts of MAH available
- ✓ NMVO sees update in real time
- ✓ Initial onboarding of MAH by BeMVO
- ✓ Limitation to one user per MAH
(cost free!)
- ✓ No bulk functionality available



Connecting MAHs in Belgium to NAMS

(Option 2)



Using NVMS Alerts as AMS

- ✓ No separate login to Belgian NAMS necessary
- ✓ All FMD Alerts of all countries in one system
- ✓ Full powerful functional scope
(Alert resolution on Batch Level, bulk handling, reporting, etc.)
- ✓ No administration on BeMVO necessary
Cost: see TCK NMVS Alerts website

<https://www.nmvs-alerts.com/prices-mah>

Using EMVO EAMS solution

- ✓ All MAH relevant FMD Alerts available
- ✓ No administration on BeMVO necessary

Free of charge

Connecting MAHs
in Belgium to NAMS

(Option 3)

Vragen?

