



# e-VIS webinar -status kring e-verifikation

6 december 2022

# RECALL OCH WITHDRAWAL I EMVS: “NORDISK BEST PRACTICE”

# Recall and withdrawal in the EMVS.

## Best Practices from the Nordic Countries

November 2022



# From the Delegated Regulation (EU) 2016/161:

## Article 40

*The marketing authorisation holder or, in case of parallel imported or parallel distributed medicinal products bearing an equivalent unique identifier for the purposes of complying with Article 47a of Directive 2001/83/EC, the person responsible for placing those medicinal products on the market shall promptly take all the following measures:*

- ***ensure the decommissioning of the unique identifier of a medicinal product which is to be recalled or withdrawn, in every national or supranational repository serving the territory of the Member State or Member States in which the recall or the withdrawal is to take place;***

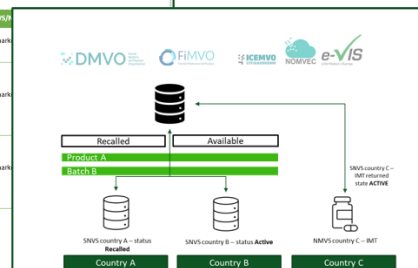
## Existing functionality for withdrawal, recall and looked packs can further secure the supply chain and patient safety. Using the EMVS is an opportunity for streamlining the processes around recall.

- Nordic NMVOs have worked together to find a best practice and recommendations for usage of status RECALLED and WITHDRAWN in EMVS.
- The Nordic countries are often seen as one market and many packs are shared between the countries.
- The first step has been to clarify how the existing functionality in the EMVS can be used in an optimal way.
- Recommendations has been aligned with national stakeholders and NCAs.
- Recommendations (including Use Cases and Q/A) aimed to be published end of 2022 by respective NMVO

Use cases for MAH

Use case	Description	MAH EMVS
Marketing authorization withdrawal	A marketing authorization is withdrawn for a product. Impacts all packs on the market subject to further distribution	Product mark markets.
Recall of all batches of a product from a whole market	Packs on the whole market are returned or destroyed, from wholesalers, pharmacies, and health care institutions. Or recall impacts only wholesalers and packs have only been distributed to wholesalers.	Batches mark markets.
Recall of batches from a whole market	Packs on the whole market are returned or destroyed, from wholesalers, pharmacies, and health care institutions. Recall impacts the whole market, e.g. wholesalers, pharmacies and healthcare institutions. Or recall impacts only wholesalers and packs have only been distributed to wholesalers.	Batches mark markets.

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Recall and withdrawal in NMVS - Nordic recommendations



Can a pack marked as recalled or withdrawn be reversed back to active status?  
No. Decommissioning a batch or a product code as recalled or withdrawn is permanent and cannot be reversed. The functionality should therefore be used with caution since a recalled batch cannot be decommissioned at the end user and therefore must be seen as "consumed" when being marked as inactive in the EMVS.

Who do I contact if I have questions about EMVS functionality to set a batch or product to status recalled or withdrawn?  
For questions regarding EMVS functionality contact EMVO helpdesk [helpdesk@emvo.eu](mailto:helpdesk@emvo.eu)

For guidance to EMVO Gateway, see EMVO Gateway User Manual (EMVO\_0038)

Contact information to Nordic NMVOs

NMVO	Web	E-mail
e-Verifikation i Sverige	e-visit	For general questions <a href="mailto:info@e-vis.se">info@e-vis.se</a> For alerts and system functionality <a href="mailto:ops@e-vis.se">ops@e-vis.se</a>
DMVO - Dansk Medicin Verifikation Organisation	<a href="http://www.dmvov.dk">www.dmvov.dk</a>	<a href="mailto:info@dmvo.dk">info@dmvo.dk</a>

End-user actions

Response NMVS	End-user action	Reporting
Response "The batch has been recalled" for packs intended to be supplied to the public:	The pack is taken out of salable stock. Verify with recall information according to local SOP and guidelines for recalls that the batch has been recalled. The pack is handled according to SOP for recalled packs.	Local deviations at end user level are handled in end-user QME. If there are reasons to suspect non-compliant actions in the supply chain, reporting is to be done to NMVO and/or NCA.
Response "The batch has been recalled" for packs intended to be decommissioned as destroyed by the end-user having the pack.	Verify with recall and guidelines for recalled. If the wholesaler (if any) Note that ops in NMVS will packs can be destroyed without decommissioning the pack.	
Response "The pack is active" for packs subject to a recall	The pack is in guidelines for recall	

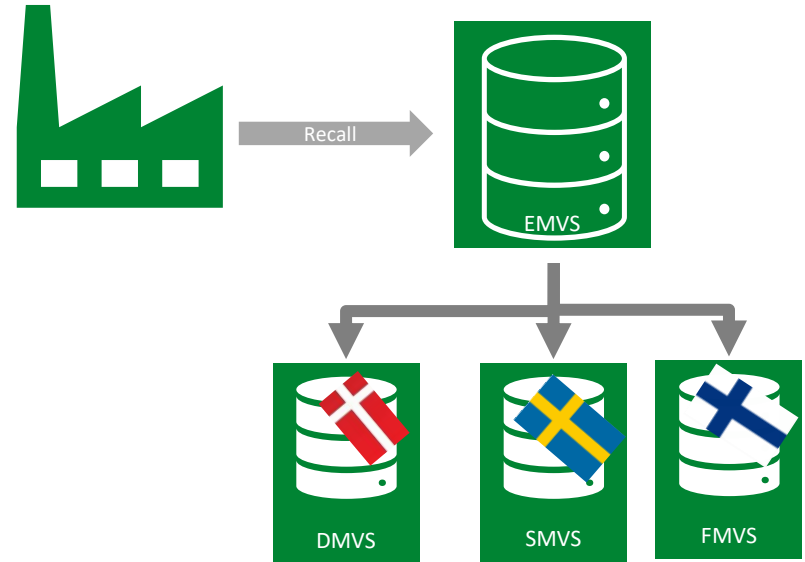
2022-11-30  
Recall and withdrawal in NMVS - Nordic recommendations

Denmark	Finland	Norway	Iceland	Sweden
<ul style="list-style-type: none"> <li>In cases The Danish Medicines Agency has assessed that a defect may have profound implications for patient safety, and a recall at patient level must be effected, they will communicate the recall, e.g. on the website of the Danish Medicines Agency.</li> <li>If a batch is recalled at pharmacy level, the recalled status in the NMVS must be done at the same time as the recall letter goes out to the relevant parties. If a batch is recalled at wholesaler level, but not recalled from pharmacies, packs must still be able to be dispensed and therefore cannot change status to Recalled in the system. In such cases, the Danish Medicines Agency will require the batch to change status at both MAH and wholesalers, so that no more packages are sent out into the supply chain, but we do not have a status in DMVS that fits this situation.</li> </ul>	<ul style="list-style-type: none"> <li>The marketing authorization holder (MAH) is responsible for planning the actions in case of a confirmed product defect and the resulting recall activities. The MAH is also responsible for the communication of the product defect and the actions taken to address it, including the decision to recall a batch/batches and instructions for wholesalers and pharmacies. The Finnish Medicines Agency Fimea oversees that the actions taken are adequate and appropriate.</li> <li>Generally, a batch should not be marked as recalled in the Finnish NMVS before the actions have been communicated to and agreed with Fimea, and the issue has been communicated to the entire Finnish distribution chain.</li> <li>In case of a marketing authorization (MA) withdrawal, the product should be marked as withdrawn in the Finnish NMVS the day when the MA cancellation takes effect.</li> </ul>	<ul style="list-style-type: none"> <li>The actor importing medicinal products to Norway, often the Market Authorisation Holder, is responsible for the actions regarding recalls of products. They must follow the agreed upon routines for recalls as specified on SIVs homepage <a href="https://siv.no/en/verktu">https://siv.no/en/verktu</a>.</li> <li>The MAH must mark the affected batch(es) as recalled for the Norwegian market in the EMVS as soon as possible after the wholesalers are notified, and not later than 24 hours after the notification to the wholesalers is issued, in order to minimize the risk for potential harmful products being dispensed to patients.</li> <li>If a product is withdrawn from the Norwegian market, the MAH must mark the product as withdrawn for the Norwegian Market in the EMVS the same day as the MA cancellation takes effect.</li> </ul>	<ul style="list-style-type: none"> <li>The MAH must mark the affected batch(es) as recalled for the Icelandic market in the EMVS as soon as possible after the wholesalers are notified, and not later than 24 hours after the notification to the wholesalers is issued.</li> <li>If a product is withdrawn from the Icelandic market, the MAH must mark the product as withdrawn for the Icelandic market in the EMVS the same day as the MA cancellation takes effect.</li> </ul>	<ul style="list-style-type: none"> <li>If recall status should be set on the recalled batch, MAH/OBP should be informed about that the batch should be marked as recalled for the Swedish market as soon as possible when the approved recall letter is distributed to wholesaler for further distribution according to the cascade principle. (For more information, see <a href="http://www.nordwebben.se">www.nordwebben.se</a>)</li> <li>MAH/OBP should mark the product code as withdrawn the same date as degradation date (comes into actions) in the national article register VASA/LIV. (For more information, see <a href="http://Hapbde.LIV-efo@nordwebben.se">Hapbde.LIV-efo@nordwebben.se</a>)</li> </ul>

No exhaustive, ref to guidelines.

# Marking a batch as recalled or a product as withdrawn in EMVS

- The OBP, under the responsibility of the MAH, marks the batch as recalled or the product code as withdrawn through the EU Hub.
- Marking a batch as recalled or a product as withdrawn is a country specific action. The OBP selects in which markets the batch or product should be marked as recalled or withdrawn. E.g. a shared batch is to be recalled in Sweden but not in Norway.
- Marking a batch to recalled and a product as withdrawn are irreversible actions in the EMVS. Correct handling is of importance to avoid unnecessary disruptions in the supply chain
- Please note!
  - The recommendations for EMVS handling are additional guidelines to existing national processes for handling recalls and product withdrawal and does **not** replace national processes.
  - The guide does not include any recommendations on how to handle returns and credit of packs.



# Recommendations for the Nordic market 1/2

- **If a batch is recalled from a whole national market should it be marked as RECALLED by the MAH/OBP in the impacted market.**
  - If the recall only impacts parts of the national market (e.g wholesaler level but not pharmacy level), parts of the batch or is still pending, the batch should **not** be marked as RECALLED. No action required in the EMVS, the batch should be in active state.
- **A product for which marketing authorisation has been withdrawn in one or several national markets should be marked as WITHDRAWN in the impacted markets.**
- **A product or batch with shared Nordic packs can either be withdrawn or recalled:**
  - From all Nordic markets
  - From one or several Nordic markets depending on the situation in the different markets.
  - A batch or product should not be marked as recalled or withdrawn if the batch or product at some point could be available for further distribution or dispensing to patients.
- A pack in active state in EMVS/NMVS subject to a recall or withdrawal according to national processes and guidelines is handled according to national existing processes for recalls and withdrawal.

# Recommendations for the Nordic market 2/2

## The EMVS is an end-to-end system

- The NMVS will inform the end-user that the pack is subject to recall or withdrawal at the point of being supplied to the public, verified or decommissioned of any reason.
- The NMVS will not inform the end-users that they have recalled or withdrawn products in their saleable stock.

## When should a batch/product be marked as recalled/withdrawn?

- A batch/product should be marked as recalled/withdrawn in close connection to, but always after the point of when the recall or withdrawal is communicated or accessible to stakeholders (pharmacies, wholesalers, and healthcare institutions).
- Please note: if a batch/product marked as recalled/withdrawn in NMVS without supporting information from the MAH can cause confusing and cause extra work for end-users.
- Since the national processes for batch recall differ in some regards in the Nordic Markets, the recommendations contain some national specifications. See next slide.



# Future improvements to streamline processes and support operations in the supply chain

Setting a batch or product code to the status recalled or withdrawn is an **irreversible action** in the EMVS and impacts the whole distribution chain in the affected markets.

- How could improved functionality for setting a **batch** as **locked** improve safety in supply chain for batches under investigation?

(And maybe avoid a shortage situation if the batch could be returned to active state)

A recall in the EMVS of a batch impact the whole batch, no differentiation can be made of where in the distribution chain the packs are located.

- Could the system be improved to differentiate which type of stakeholder who should be notified of a recall situation. E.g a recall from wholesaler level or a recall all the way to pharmacy level?

Packs belonging to a recalled batch or withdrawn product can not be decommissioned as destroyed in the EMVS.

- Can the system be improved with better traceability if able to identify if and by which end-user a recalled pack has been destroyed?

Ref. to Article 35 in the DR (EU) 2016/161. [...] *shall maintain a complete record ('audit trail') of all operations concerning a unique identifier [...]*

# Contact

NMVO	Web	E-mail
<b>DMVO - Dansk Medicin Verifikation Organisation</b>	dmvo.dk	<a href="mailto:Info@dmvo.dk">Info@dmvo.dk</a>
<b>e-VIS - e-Verifikation i Sverige</b>	e-vis.se	For general questions: <a href="mailto:info@e-vis.se">info@e-vis.se</a> For alerts and system functionality: <a href="mailto:alerts@e-vis.se">alerts@e-vis.se</a>
<b>FiMVO - Finnish Medicines Verification Organisation</b> <b>/ Suomen Lääkevarmennus Oy</b>	laakevarmennus.fi	For alerts and technical questions: <a href="mailto:nmvs@fimvo.fi">nmvs@fimvo.fi</a>
<b>ICEMVO - Lyfjauðkenni ehf</b> <b>/ Icelandic Medicines Verification Organisation</b>	lyfjauðkenni.is	For general questions: <a href="mailto:info@lyfjauðkenni.is">info@lyfjauðkenni.is</a>  For alerts and system functionality: <a href="mailto:info@lyfjauðkenni.is">info@lyfjauðkenni.is</a>
<b>NoMVO - Norwegian Medicines Verification Organisation</b>	nomvec.no	For MAHs: <a href="mailto:mahsupport@nomvec.no">mahsupport@nomvec.no</a>  For end users: <a href="mailto:ProdSPOC@nomvec.no">ProdSPOC@nomvec.no</a>

## A Glimpse into EMVS

28 National Medicines  
Verification Systems  
connected to the EU Hub



More than 10 billion  
medicines packs  
uploaded into the European  
Medicines Verification  
System (EMVS) per year

108.212 Pharmacies  
4.033 Wholesalers  
6.355 Healthcare  
Institutions  
connected to the EMVS



More than 2.800  
Pharmaceutical  
Companies connected to  
the EMVS

The EMVS Community places its  
focus on guaranteeing patients'  
access to authentic medicines.



"The European Medicines  
Verification System is keeping  
patients safe in Europe – this  
is only achieved with the  
collaboration of all our  
European partners."

Sónia Queirós, EMVO's Chief  
Operating Officer



EMVS - a  
unique  
European  
collaboration  
success story



EMVO & the  
NMVOs  
exchange best  
practices and  
knowledge



EMVS - 24  
Working  
Groups  
working  
towards  
continuous  
improvement

### The EMVS Community Principles

1. Increase patients' safety against falsified medicines in Europe.
2. EMVS – European Collaboration.
3. Technical Excellence – the EMVS is continuously developing thanks to the input and support of its many collaborators.

"Since the start of the EMVS the  
great collaboration between  
EMVO and NMVOs has proven to  
be highly efficient and effective in  
protecting the pharmaceutical  
supply chain against intrusion of  
falsified medicines."



Christoph Lendl, AMVS Managing  
Director

# TACK FÖR IDAG!