Recall and withdrawal in NMVS – Nordic recommendations

Definitions

Delegated Regulation	Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use
EMVS	European Medicines Verification System including EU Hub and all connected NMVSs
NMVO	National Medicines Verification Organisation responsible for governing national NMVS
NMVS	National Medicines Verification System – the national/market specific part of the EMVS
End-user	Pharmacy, wholesaler, distributor or healthcare providers
MAH	Marketing Authorisation Holder
NCA	National Competent Authority
OBP	On Boarding Partner. Legal entity of MAH that manages uploading of product and pack data in EMVS via the EU hub.

Definitions of EMVS status Recall and withdrawn

EMVS/NMVS Status	**Definition**
RECALLED	A batch or batches have been recalled
WITHDRAWN	A product has been withdrawn

Introduction

The delegated regulation states that a batch subject to recall or a product subject to withdraw should be decommissioned in the EMVS system for the affected markets. Usage of recall and withdrawal functionalities in the EMVS can further improve security in the medicine distribution by preventing that recalled or withdrawn packs are dispensed to patients.

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 *a) ensure the decommissioning of the unique identifier of a medicinal product which is to be recalled or withdrawn, in every national or supranational repository serving the territory of the Member State or Member States in which the recall or the withdrawal is to take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

However, processes for batch recall and product withdrawal vary in different markets and the EMVS functionality does not match the granularity in the different processes. Hence there is a need for alignment in the usage of recall and withdrawal functionalities in the EMVS to ensure optimal usage.

Important to note is that:

- EMVS functionalities and guidelines regarding these functionalities do not replace national guidelines and procedures for recalls and product withdrawal.
- The NMVS does not track an end-user's stock, and only alerts and warns the end-user of a recall/withdrawal when they verify or try to change pack status. The end-user receives information of the batch/product state in NMVS at the point of verifying or decommissioning the physical pack.

Hence, it is important that national guidelines still are followed so that end-user receives sufficient information to remove recalled/withdrawn packs from saleable stock as soon as possible.

These recommendations have been set up by the NMVOs of the Nordic countries:

- e-VIS - e-Verifikation i Sverige
- DMVO - Dansk Medicin Verifikation Organisation
- FiMVO - Finnish Medicines Verification Organisation / Suomen Lääkevarmennus Oy
- ICEMVO - Lyfjaauðkenni ehf / Icelandic Medicines Verification Organisation
- NoMVO - Norwegian Medicines Verification Organisation

General recommendations on how to use recall and withdrawal functionality in the EMVS.

Only 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, parts of the batch or is still pending the batch should not be marked as RECALLED and left in active state.

The status recall and withdrawn is a country specific action

The MAH/OBS can choose in which markets where the batch is uploaded where the batch should be marked as recalled.

The batch will remain active in the countries where the batch is uploaded and where the batch is not marked as recalled.

If a pack is verified in a country where the batch is not uploaded the status will be fetched via an intermarket request:

- The batch will be seen as recalled if the batch is recalled in all markets where the batch is uploaded
- The batch will be seen active if the batch is active in one or more markets where the batch is uploaded.

A batch with shared Nordic packs can either be recalled:

- **From all Nordic markets**
- **From one or several Nordic markets depending on the situation in the different markets**

A product for which marketing authorisation has been withdrawn in a national market should be marked as WITHDRAWN in the impacted market.

The status recalled and withdrawn are irreversible actions

Please note! 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**.

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.

- If a batch is marked as recalled or if a product is marked as withdrawn in the EMVS **this status cannot be reactivated.**
- If a batch is marked as recalled or a product is marked as withdrawn in the EMVS **the packs cannot be decommissioned or dispensed to patient.**

The status WITHDRAWN on a product also prevents the uploading of additional batches to the system for the affected markets.

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

A batch/product marked as recalled/withdrawn without supporting information from the MAH can be confusing for end-users and cause extra work for them since the concerned packs can be in saleable stock in the pharmacy and the recalled status will only be revealed at the point of dispense and in worst case in front of a patient.

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).

Since the national processes for batch recall differ in some regards, detailed instructions of when the batch/product should be decommissioned are described below:

Denmark

The Danish Medicines Agency will initiate a recall of the affected batches together with the company, if an error is discovered involving a medicine that is on the Danish market or is exported from Denmark.

The Danish Medicines Agency assesses how far down the chain of distribution the recall should be effected (wholesaler, pharmacy, patient). An assessment of whether the authorities in other countries need to be informed via the Rapid Alert System is performed.

In the event of a recall, the company must submit the following documentation to the Danish Medicines Agency:

- Copy of the recall letter
- An account of preventive measures
- Any other relevant data

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.

If a batch is recalled at pharmacy level, the recalled status in the DMVS 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.

Information about recall normally goes to wholesalers, possibly to pharmacies and, in rare cases, even to the public. If a batch is withdrawn from the market, the information can be published on the Danish Medines Agency website.

In Denmark there is no distinction between withdrawn and recall.

Finland

The marketing authorisation 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.

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.

In case of a marketing authorisation (MA) withdrawal, the product should be marked as withdrawn in the Finnish NMVS the day when the MA cancellation takes effect.

Iceland

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.

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.

Norway

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 Norwegian Medical Products Agency (DMP)s homepage dmp.no.

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.

Since DMP allows continued sale for three months after the date a product is withdrawn (discontinuation of the MA) from the Norwegian market, the MAH must mark the product as withdrawn for the Norwegian Market in the EMVS only after this period has passed.

Sweden

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 *www.rodawebben.se*)

MAH/OBP should mark the product code as withdrawn the same date set as deregistration date (comes into actions) in the national article register VARA/LiiV. (For more information, see *Handbok LiiV – eHälsomyndigheten*)

Use cases for MAH

Use case	Description	MAH EMVS/NMVS action
Marketing authorisation withdrawal for all markets	A marketing authorisation is withdrawn for a product. Impacts all packs on the market subject to further distribution	Product marked as WITHDRAWN in affected 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. 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 marked as RECALLED in affected 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 marked as RECALLED in affected markets.

Recall of batches from the Nordic market	Packs on the Nordic 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 marked as RECALLED in Nordic markets.
Pending recall	Batches are taken out from saleable stock during investigation of potential authorisation withdrawal. Packs may later be destroyed/returned or put back into saleable stock. Impacts all packs on the market subject to further distribution.	No action – batch left in active state
Partial recall	Packs on the whole market are returned or destroyed. The recall only affects some parts of the distribution chain, e.g., recall from wholesalers, but not from pharmacies and healthcare.	No action – batch left in active state
Marketing of a medicinal product is discontinued in a specific market	MAH discontinues the marketing of a product in a specific country. The product is no longer available for distribution from MAH. Packs on the market and in pharmacies can still be dispensed to patients.	No action – product code left in active state

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 saleable 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 QMS. 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.	The pack can be destroyed without decommissioning the pack. Verify with recall information according to local SOP and guidelines for recalls that the batch has been recalled. If recall information is missing, contact wholesaler (or MAH) for further information. Note that operation to decommission as destroyed in NMVS will not be successful since only active packs can be decommissioned as destroyed.	Local deviations at end-user level are handled in end-user QMS. 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 pack is active” for packs subject to a recall	The pack is handled according to local SOP and guidelines for batch recall.	No reporting required

Response ”The product has been withdrawn” for packs intended to be supplied to the public	The pack is taken out of saleable stock. Verify with withdrawn information according to local SOP and guidelines for product withdrawal that the product is withdrawn. The pack is handled according to SOP for withdrawn products.	Local deviations at end-user level are handled in end-user QMS. 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 product has been withdrawn” for packs intended to be decommissioned as destroyed by the end-user having the pack.	The pack can be destroyed without decommissioning the pack. Verify with withdrawn information according to local SOP and guidelines for product withdrawal that the product is withdrawn. Note that operation to decommission as destroyed in NMVS will not be successful since only active packs can be decommissioned as destroyed.	Local deviations at end-user level are handled in end-user QMS. 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 pack is active” for withdrawn packs	The pack is handled according to local SOP and guidelines for product withdrawal.	N/A
Response ”The product has been withdrawn” for packs in healthcare institutions not subject to further sales	No action required	N/A

Questions & Answers

1. Can status change in EMVS/NMVS-system replace national guidelines for recalls and product withdrawal?

No, please note that this recommendations on how to use Recall and withdrawn status in the EMVS should be seen as a complementary guide to existing national guidelines.

Status change in EMVS is a complement to further secure medicinal authenticity. National guidelines for communication of recalls and withdrawal should always be followed.

2. Can batch/es belonging to a product code previously marked as withdrawn be marked as recalled in EMVS?

Yes. However, the status returned to end-user will be withdrawn for affected packs.

3. Can a batch have status recalled or withdrawn in one country but still active in another country?

Yes. Both recall and withdrawal functionality are market specific. This means that the MAH/OBP will have as input the market (or markets) in which the recall or withdrawal will be effective. Therefore, a Multi-Market Product can be recalled/ withdrawn in one market while active in other.

MAH sets target affected market(s) when issuing batch recall in EMVS.

4. Can parts of a batch be marked as recalled?

No. If a batch is marked as recalled in a country *all active packs within that batch* will get the status recalled.

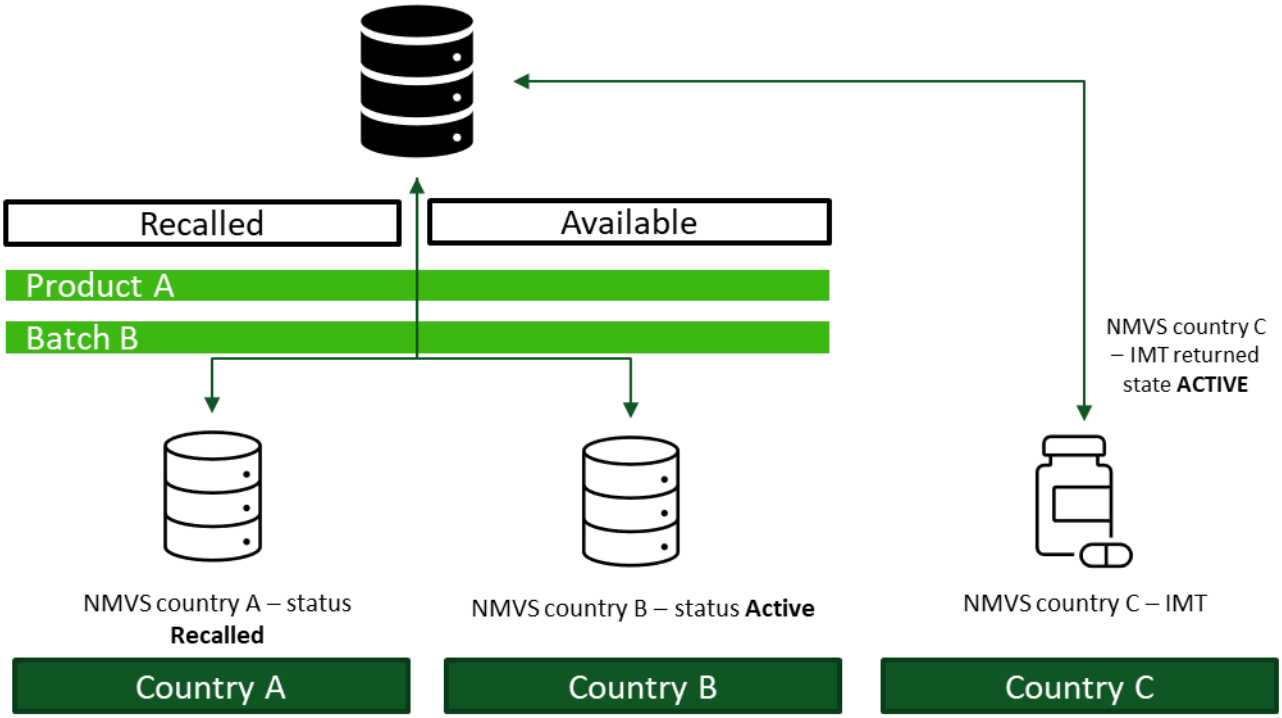
5. Can a pack be recalled in NMVS/EMVS only at wholesaler level?

No. Any end-user in supply chain will be informed that the batch of the pack is recalled when verifying the pack.

A batch with status recalled cannot be decommissioned or supplied in NMVS by any end-user through the supply chain.

6. If a pack is active in one market, but recalled in another, when an IMT is made which status is returned?

Returned status will be ACTIVE! EMVS HUB prioritise countries where batch is in active state.



7. Can a pack marked as recalled or withdrawn be reversed back to active state?

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 therefor most be seen as “consumed” when being marked as inactive in the EMVS.

8. Can decommissioning of batch or product be made in NMVS in a mock recall?

No. Decommissioning a batch or a product code as recalled or withdrawn is permanent and cannot be reversed. Hence the operational environment of EMVS should not be used to decommission batch or product in a mock exercise.

9. If a batch is recalled in the EMVS, will the status of already decommissioned packs also change to Recalled?

If a pack has been decommissioned as supplied the pack status will stay in status supplied even though the batch has been recalled in the EMVS.

The batch will however get the status Recalled in the EMVS, depending on the end-user system, the recall status can be available for decommissioned packs to the end-user.

10. If an end-user attempts to reactivate a pack that has been decommissioned as supplied at the same location within 10 days, but the batch has later been marked as recalled. Will the end-user be able to reactivate the pack?

No. The end-user will not be able to reactivate the pack to active state. The pack cannot be decommissioned since the batch is recalled. The same applies if the product code would be withdrawn.

11. 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-medicines.eu

For guidance to EMVO Gateway, see EMVO Gateway User Manual (EMVO_0038)

12. If a pack is recalled only due to commercial reasons, should the batch then also be marked as recalled in EMVS?

If a batch would be recalled for only commercial reasons the same rules would still apply for the recall. A batch that is recalled from a whole market should be marked as recalled in EMVS regardless of the reason. Note that a batch that has been recalled in a market in EMVS never can be distributed further or supplied to the public.

13. If the batch is recalled due to commercial reasons, the batch should always be recalled in the EMVS after the last selling date. Please note that a recall for only commercial reason may not be permitted in all Nordic markets. Can the recall functionality be tested by an MAH in a mock-recall of a batch?

Do not make any status changes in the EMVS in a mock recall. The action of marking a batch as recalled is irreversible. Instead, during a mock-recall, test the knowledge and communication routes within your company. Test instead if EMVS actions are included in the routine for a recall and if the routines describe how to recall a batch from one or several markets in EMVS.

14. We have a shared batch between Norway and Denmark. When released, the batch was however only uploaded to the Danish system and not to the Norwegian system. The batch will now be recalled in Denmark, but not in Norway. Can we recall the batch in EMVS so that the packs are seen as recalled in Denmark but active and available to be decommissioned in Norway?

Since the packs are not available in the Norwegian system the status will be fetched from the Danish system. Marking the packs as recalled in the Danish system will prevent the packs from being decommissioned in Norway.

The situation should be handled as a deviation since the packs were not correctly uploaded when released to the markets.

Contact information to Nordic NMVOs

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

Contact information to EMVO

EMVO	Web	E-mail
European Medicines Verification Organisation	emvo-medicines.eu	helpdesk@emvo-medicines.eu

Document history

Date updated	**Desciption of change**
2023-01-10	New document
2023-02-13	Minor editorial updates
2024-12-02	Clarifications under *General recommendations on how to use recall and withdrawal functionality in the EMVS*. New and updated questions under *Questions & Answers*