Recall and withdrawal in NMVS- BeLux 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Definitions of EMVS status Recall and withdrawn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WITHDRAWN	A product has been withdrawn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functionalities in the EMVS can further improve security in the medicine distribution by preventing that recalled or withdrawn packs are dispensed to patients.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
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> *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 *a) ensure the decommissioning of the unique identifier of a medicinal product which is to be recalled or withdrawn, in every national or supranational repository serving the territory of the Member State or Member States in which the recall or the withdrawal is to take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 Belgium and Luxembourg.

- BeMVO – Belgian Medicines Verification Organisation
- LMVO – Luxembourg 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, in case of Belgium this includes the Luxemburg 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.

A batch with multi-market packs can either be recalled:

- **From all markets**
- **From one or several markets depending on the situation in the different markets. Attention Luxembourg has no separate NMVS system, therefore batches should only be marked as recalled or withdrawn by the MAH if the recall or withdrawal is valid for both countries. If the recall is not valid for both countries the batch should not be marked as recalled or withdrawn in the EMVS system and only the APB system should be used.**

A product for which marketing authorisation has been withdrawn in a national market should be marked as WITHDRAWN in the impacted market.

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 by the pharmacist 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).

Which procedure should be followed to recall or withdraw a product from the Belgian and/or the Luxembourg market?

The Medicines Control Service (DGO / SCM) from the Belgian Pharmacists organisation (APB) organises the withdrawal of the market (Belgium and the Grand Duchy of Luxembourg) of non-compliant products, of products with cessation of commercialisation or deletion/suspension of registration/authorisation.

The marketing authorisation holder needs to provide all necessary information on the recall or withdrawal by e-mail to dgo_scm@apb.be by using one of the following standard forms.

https://www.apb.be/SiteCollectionDocuments/SCM-DGO%20DOCUMENTS/BROCHURE-DOCUMENT-RETRAITS-INTREKKINGEN/Formulier-Interactief-Intrekkingen-DGO.pdf

https://www.apb.be/SiteCollectionDocuments/SCM-DGO%20DOCUMENTS/BROCHURE-DOCUMENT-RETRAITS-INTREKKINGEN/Formulaire-Interactif-Retraits-SCM.pdf

This procedure needs to be followed before entering a recall or withdrawal on the EMVS.

Use cases for MAH

Use case	Description	MAH EMVS/NMVS action
Marketing authorisation withdrawal	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.
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	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

Q&A

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.

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.

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.

Can parts of a batch be marked as recalled?

No.

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

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

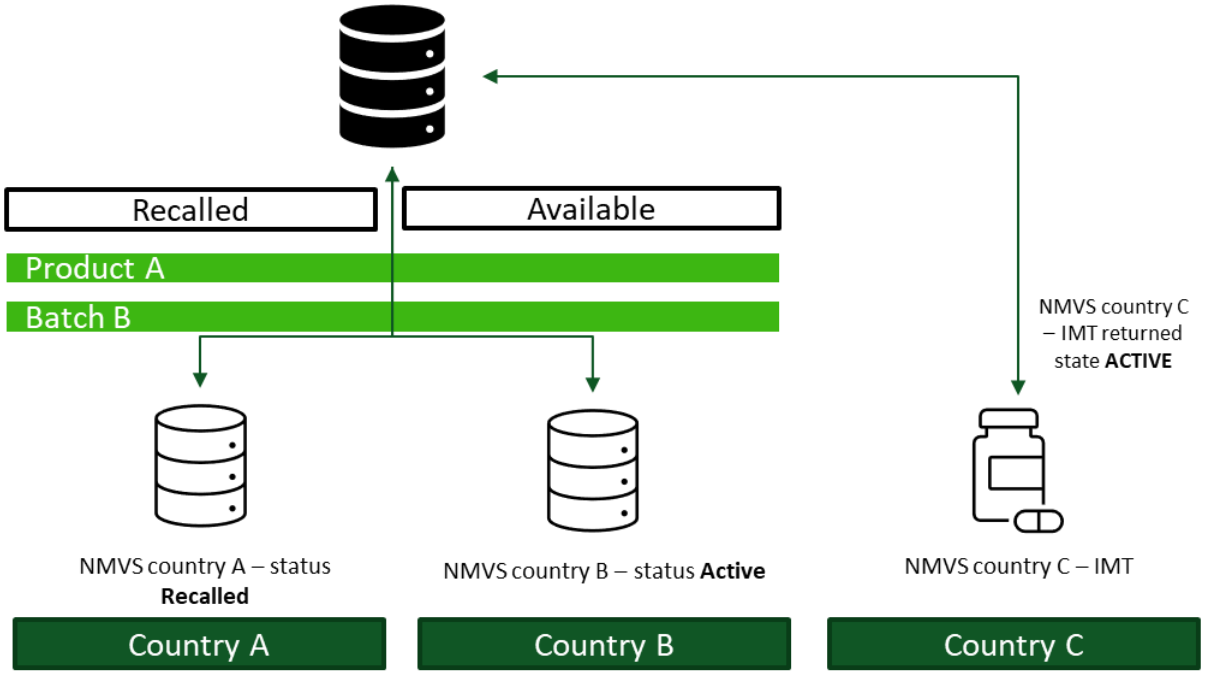
No.

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.

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

Returned status will be ACTIVE! EMVS HUB prioritise countries where batch is in active state. (see diagram below)



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.

Can decommissioning of batch or product be made in SMVS 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.

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)

Contact information to BeMVO and LMVO

NMVO	Web	E-mail
BeMVO – Belgian Medicines Verification Organisation	www.Bemvo.be	For general questions info@bemvo.be For alerts and system functionality alerts@bemvo.be
LMVO - Luxembourg Medicines Verification Organisation	www.LMVO.lu	Info@lmvo.lu

Contact information to EMVO

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