

# Description of functionality – Mark packs as Locked

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## 1 Introduction

This document has 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 - Icelandic Medicines Verification Organisation / Lyfjauðkenni ehf
- NoMVO - Norwegian Medicines Verification Organisation

The purpose of this document is to inform MAHs and end-users of the functionality to mark packs as locked in EMVS. There are no legal requirements to use the functionality and hence usage of the functionality is voluntary.

## 2 Background

The functionality to mark a pack as locked is described in the EMVS URS and is available as an option to use in all national systems.

### 2.1 Status Locked and the Delegated regulation

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The functionality to mark a pack as locked is not described as a legal requirement in the delegated regulation (EU) 2016/161. For this reason, there are no legal requirements for any supply chain actor to mark a pack as locked.

However, the functionality can provide added value and security in preventing medicines in quarantine or under investigation entering in or going back into the supply chain. The functionality goes well with the purpose of the delegated regulation of preventing falsified medicines from reaching patients through the legal supply chain.

### 2.2 Description of locked in EMVO URS Lite

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Mark pack as locked is described as below in EMVS URS Lite (4.3.2.3.5 Locked)<sup>1</sup>

*The “Locked” status is used where the pack(s) may be subject of an irreversible state change operation however the full investigation has not yet been concluded. “Locked” is therefore used to prevent continued use of a product until the investigation has been concluded. The use case starts with identifying the single product pack or bulk of product packs as subject to further investigation which can be conducted by a wholesaler; in this case the product pack must be reported as “Locked” to the national systems.*

*Once the product pack is reported to the National System as “locked”, the National System will check if the product is a multi-market type and if so, will transfer the new product pack status to the European Hub for National System(s) synchronisation. The product pack gets decommissioned and obtains the new indication “Locked”.*

*This is a temporary state. Once the investigation is completed the pack or bulk of packs can be either set again to its previous indication or will be marked as being decommissioned with another indication, e.g., “Stolen”.*

The functionality to mark as locked is hence intended to work as a status in which the pack is temporarily ‘decommissioned’ pending further investigation or action.

For other decommission statuses, being permanent statuses, the state implies that the pack should no longer be in the supply chain. For the locked status, which is a *temporary* state, the pack can remain in the supply chain during investigation, but in quarantine/separated from saleable stock.

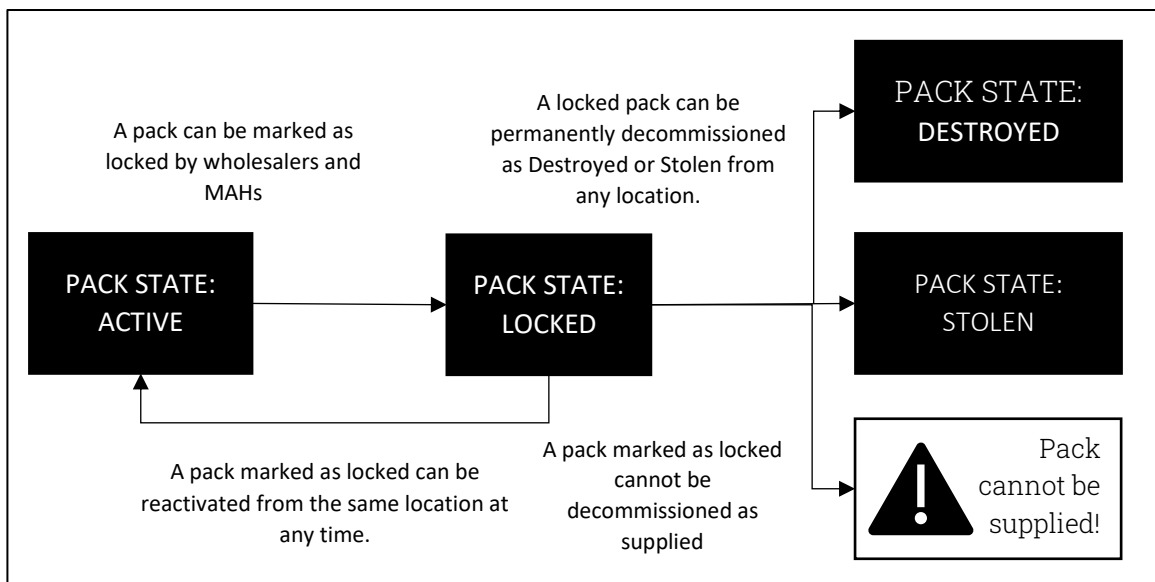
A locked pack should not remain in the status locked as a final state but should be reactivated to change the state into active or decommissioned to a final state of destroyed or stolen.

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<sup>1</sup> <https://emvo-medicines.eu/new/wp-content/uploads/EMVS-URS-Lite.pdf>

### 3 Functionality to mark a pack as locked

- **A pack can be marked as locked by wholesalers and MAHs**
- Marking a pack as locked prevents the pack from being supplied to the public
- **Marking a pack as locked is a pack level status change** and the status change should only be performed by the actor in physical possession of the pack.
- **A pack marked as locked can be reactivated from the same location at any time.** If a locked pack should be returned to supply chain the pack must be reactivated to ACTIVE state
- **A locked pack can be permanently decommissioned as Destroyed or Stolen from any location.**



#### 3.1 A pack can be marked as locked by wholesalers and MAHs

The operation to mark a pack as locked can be performed by wholesalers and MAHs.

Pharmacies (including health care providers) **cannot** mark a pack as locked.

#### 3.2 Marking a pack as locked prevents the pack from being supplied to the public

The status locked indicates that the pack is temporarily removed from the available stock and should therefore not be subject to being handed out to patients or further on into the supply chain. For this reason, the EMVS does not allow a pack in status locked to be decommissioned as supplied.

A pack in status locked found in available stock at a pharmacy or wholesaler should be put in quarantine and subsequently be investigated and reported.

### 3.2.1 Decommission a locked pack as supplied generates alerts

If an end-user or MAH attempts to mark a locked pack as supplied the attempt will get rejected and an alert will be generated. The EMVS will also not allow a locked pack to be decommissioned as SAMPLE, FREE SAMPLE, EXPORTED or CHECKED OUT.

If an end-user verifies a locked pack, the end-user will be informed that the pack is in status locked. Since an end-user can verify a pack to reassure that a pack successfully has been put in status locked, no alert will be generated when a locked pack is verified.

A locked pack found in available stock should be put in quarantine and subsequently be investigated and reported.

## 3.3 Mark a pack as locked is a pack level status change

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To mark a pack as locked is a **pack level** change, meaning that the status locked is linked to the specific serial number of the pack being locked. Therefore, the status change only impact that single package.

In comparison, the status 'Recalled' is a batch level status and is hence linked to the batch information in the EMVS and not to the physical pack.

See Appendix Table 1, Overview of pack statuses.

### 3.3.1 Mark a pack as locked should only be performed by the actor in physical possession of the pack

The marking of a pack as locked is linked to a physical pack and *the status change should only be performed by the actor in physical possession of the pack.*

A MAH has access to all unique identifiers of a batch and can technically decommission packs even though not being in physical possession of the pack. However, a pack status change should never be performed by a MAH if the MAH is not in physical possession of the pack.

Marking a decommissioned pack as locked raises an alert. Marking a pack as locked means that the pack is temporarily removed/withheld from the supply chain, for example, to be quarantined during ongoing investigation.

When a pack is supplied or removed from the supply chain e.g. as a sample or due to being destroyed, it must be decommissioned to the corresponding inactive pack state. If that specific pack is later marked as locked, an alert will be raised since no one in the supply chain (and with access to the EMVS) should be in possession of the pack. (Supplied means that the pack has been handed to a patient.)

### 3.3.2 Comparison with the batch status Recalled and product status Withdrawn

The status 'Recalled' is a batch level status and is hence linked to the batch information in EMVS and not to the physical pack.

If the MAH changes the batch level status to 'Recalled' and some packs in the batch are already decommissioned as supplied, no exceptions will be triggered. The pack decommissioned as supplied will remain as SUPPLIED but the batch status of all packs will be changed to RECALLED. The batch status RECALLED will prevent decommissions and further

change of the pack level status of ACTIVE packs. Like 'Recalled' there is also a product level status for withdrawal of a whole product, i.e., 'Withdrawn'.

For information on the Recall and Withdrawal functionality, please see Recall and withdrawal in NMVS – Nordic recommendations

### 3.4 A locked pack can be reactivated from the same location at any time

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There is no time limit for when a locked pack can be returned into an active status. However, the reactivation must be performed **at the same location** that marked the pack as locked and within the expiry date of the pack. An exception will be triggered if another end-user tries to reactivate a pack marked as locked at another location.

If a pack has been decommissioned as supplied, exported, sample, free sample or checked out, and needs to be returned to active status, it must be reactivated within 10 days at the same location. This 10-day time limit does not apply to the locked pack status.

#### 3.4.1 A locked pack must be reactivated when returned to the supply chain

If a locked pack is to be returned to supply chain the pack must be reactivated to ACTIVE state. Only packs in ACTIVE state can be supplied to the public or distributed further in the supply chain.

If a locked pack is by mistake distributed further in the supply chain, the pack cannot be dispensed to patients since the status locked will prevent a pharmacy from decommissioning the pack as supplied.

As for other pack statuses, if the batch has been recalled or the product code has been withdrawn in the EMVS, reactivation of the pack is no longer possible. The reason for this behaviour is that a pack belonging to a recalled batch or withdrawn product code should never be put back in available stock.

### 3.5 A locked pack can be permanently decommissioned as Destroyed or Stolen from any location

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In the general logic of the EMVS an already inactive pack cannot be decommissioned again to another status and a transaction to decommission an already decommissioned pack would generate an exception or alert. If such a status change is required, the pack must first be reactivated to active status before any decommission can be done.

However, a pack in status Locked can be decommissioned directly to the status Stolen or Destroyed from any location and at any time.

Once the pack has been decommissioned to status Stolen or Destroyed it is no longer possible to reactivate the pack to ACTIVE state.

## 4 Questions and Answers

**Can the status locked be used on a whole batch during a pending recall to prevent pharmacies and wholesaler to dispense or further distribute the packs?**

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The status locked should not be applied on a whole batch during a pending recall.

The status locked is a *pack* level status change and is therefore linked to the handling of a physical pack. If all packs of a batch already in the supply chain were to be marked as locked, all packs which have been previously decommissioned by pharmacies and wholesalers would generate alerts. Marking a whole batch or a bulk of packs as locked without being in physical possession of the packs is to be considered a misuse of the system.

**We have by mistake distributed a pack in status locked to a pharmacy. The pack can be disposed of by the pharmacy holding the packs. Can the pharmacy in possession of the pack decommission the pack as destroyed?**

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Yes. The pharmacy can decommission the pack as destroyed. A locked pack can be permanently decommissioned as destroyed or stolen from any location. If the locked pack in this case should be disposed of by the pharmacy, the pharmacy can decommission the locked pack as destroyed. The pharmacy cannot hand out a locked pack to a patient.

**We are performing a recall of a batch in market. Should we ask the wholesaler in that market to reactivate locked packs to status active before we perform the recall in EMVS?**

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No, the packs can be left in status locked. The batch status recall will prevent the packs from being reactivated. The packs will stay in status locked, but since the packs in the recalled batch will not remain in the supply chain there is no requirement to reactivate the packs.

Furthermore, packs should only be reactivated when the pack is put back in the supply chain. Since the packs are to be recalled the packs should not be reactivated.

## 5 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 NMVS's
EMVO	European Medicines Verification Organisation the organisation responsible for governing the EU hub.
EMVO URS Lite	Document published by EMVO to provide an overview of the basic principles and main elements of the EMVS that are governed and/or operated by the European Medicines Verification Organisation (EMVO) and the National Medicines Verification Organisations (NMVO's).
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 provider
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.
Exception	A warning to the end-user that an operation or request to the EMVS has not been carried out as expected. For example, it could be that a pack is not found in the EMVS or that a status change cannot be performed.
Alert	An alert is an exception which is deemed as critical and therefore should be notified. Alerts, therefore, produce notifications. The alert notification is sent to the NMVO and NCA. The alert is assigned a unique alert ID.

## Document history

Date updated	Description of change
2025-02-07	New document

# Appendix

Table 1, Overview of pack statuses

Data level	Use case	Status after decommissioning	Who can change status*				Can reactivate/undo?
			Manufacturer	Par. Distributor	Pharmacist	Wholesaler	
Product level	Withdrawal of product from market	Withdrawn	X				NO
Batch level	Recall batch from market	Recalled	X				NO
Pack level	Supply pack to the public	Supplied	X	X	X	X	Within 10 days at the same location
	Re-packaged by parallel distributor	Checked-Out		X			Within 10 days at the same location
	Export pack from EU	Exported	X	X		X	Within 10 days at the same location
	Decommission pack as Stolen	Stolen	X	X		X	NO
	Decommission pack as Destroyed	Destroyed	X	X	X	X	NO
	Decommission pack as Free sample	Free Sample	X	X		X	Within 10 days at the same location
	Decommission pack as Sample	Sample	X	X	X	X	Within 10 days at the same location
	<i>Mark pack as Locked</i>	<i>Locked</i>	X	X		X	<i>At any time at the same location.</i>

\*Manufacturers, including parallel distributors, are connected via and perform status changes via the EMVS Hub. Pharmacies (including health care providers) and wholesalers are connected via and perform status changes via the national NMVS.