e-VIS webinar
-status kring e-verifikation

6 december 2022

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RECALL OCH WITHDRAWAL I EMVS: “NORDISK BEST PRACTICE”

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Recall and withdrawal in the EMVS.

Best Practices from the Nordic Countries

November 2022

From the Delegated Regulation (EU) 2016/161:

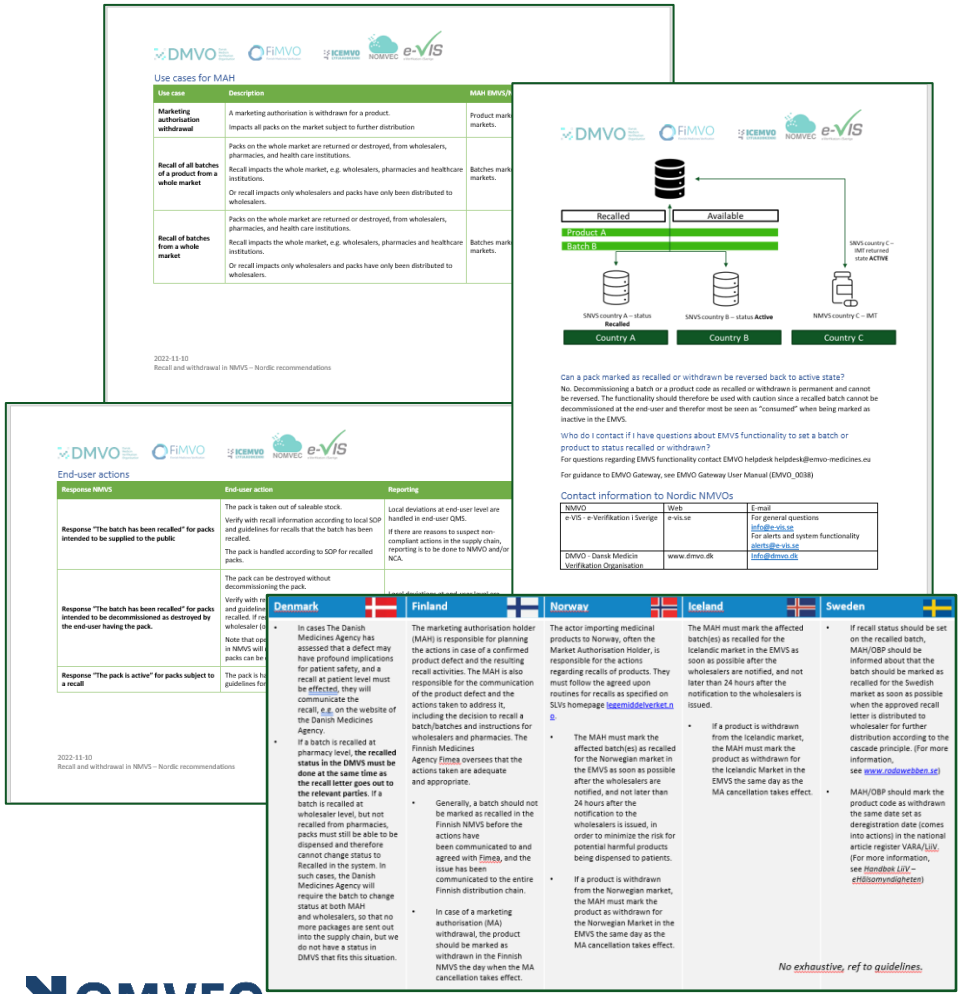
Article 40

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- ***ensure the decommissioning of the unique identifier of a medicinal product which is to be recalled or withdrawn**, in every national or supranational repository serving the territory of the Member State or Member States in which the recall or the withdrawal is to take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

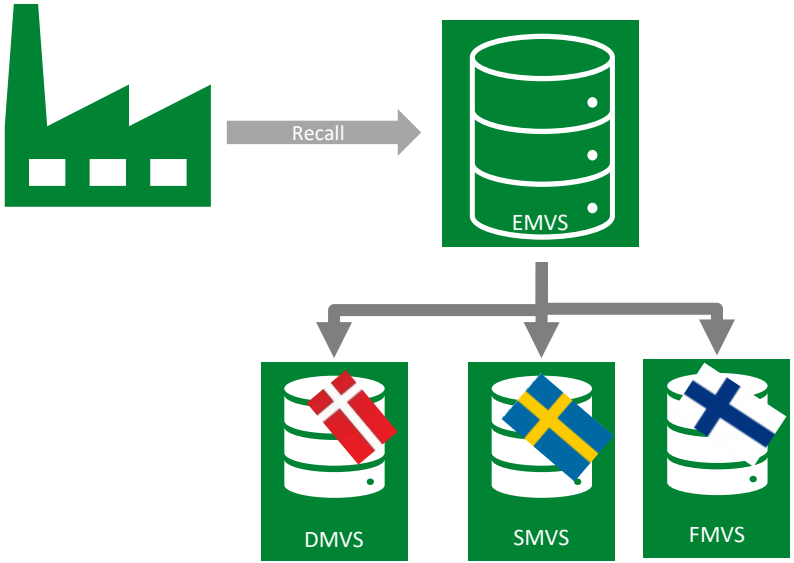
Existing functionality for withdrawal, recall and looked packs can further secure the supply chain and patient safety. Using the EMVS is an opportunity for streamlining the processes around recall.

- Nordic NMVOs have worked together to find a best practice and recommendations for usage of status RECALLED and WITHDRAWN in EMVS.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**



Marking a batch as recalled or a product as withdrawn in EMVS

- The OBP, under the responsibility of the MAH, marks the batch as recalled or the product code as withdrawn through the EU Hub.
- Marking a batch as recalled or a product as withdrawn is a country specific action.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.

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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.	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.	Packs belonging to a recalled batch or withdrawn product can not be decommissioned as destroyed in the EMVS.
• 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)	• 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?	• 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 [...]*

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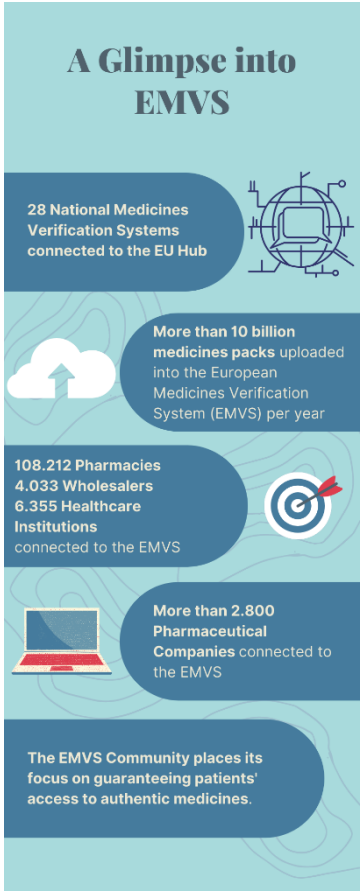

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