



LETTER OF ANNOUNCEMENT
Decommissioning of products: use of correct statuses

25th May 2021

EMVO have been made aware that some OBPs undertake activities that are not in line with correct and compliant system use.

When undertaking decommissioning activities on packs or batches, the correct transaction must be processed to set the pack status to its intended state. Performing an **incorrect transaction** can result in the generation of a **large number of alerts** and could place the status of the packs and/or batch into a non-compliant state.

For example, using the status “Locked”, which is usually used when the pack(s) maybe subject to an irreversible state change operation, instead of the status “Batch recall” is firstly not allowed and moreover, it will generate a large number of alerts within the system and provides the potential for the recalled batches to be taken out of recall and thus supplied to patients. **This practice must cease.**

OBPs are responsible for the adoption of systems, connected to the EMVS that can **adequately perform the duties required** by the Falsified Medicines Directive, the Delegated Regulation and the EMVS URS.

Therefore, EMVO requires that all OBPs ensure that their **system offers** all possible transactions enabling the compliant execution of MAH (OBPs) responsibilities as described in the FMD, DR and the EMVS URS.

Should you have questions, please do not hesitate to contact our Helpdesk.

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EMVO_LoA_0185