Guidance to NMVOs and End Users on how to handle Covid-19 vaccines in the NMVS

- Covid-19 vaccines will be serialised starting Q1/21.
- Some companies will use a common, pan-European GTIN for their vaccines, others will use same GTIN for certain market clusters.
- The Covid-19 Task force recommends data upload only to a certain number of countries, leaving the rest to use IMT transactions. Please click here to see OBP guidance.
- Any questions regarding local decommissioning rules, supply chain practices or alert handling guidance should be directed at local NCAs/health authorities.
- Questions for the Covid-19 task force can be sent to maija.gohlke-kokkonen@fimvo.fi The TF will issue revised guidance as issues arise.

Distribution of Covid-19 vaccines will vary between the Member States and it is difficult to have a clear overview of decommissioning rules or potential new End Users to be connected to the NMVS.

Even with the lack of information, it is critical that NMVOs are prepared and act quickly when issues arise. Adhering to FMD regulations is particularly important with such high-profile products but the EMVS should not be the cause for delay in getting populations vaccinated. The Task force has compiled some things to consider on a national level regarding onboarding users, decommissioning and alert handling.

- In some countries new decommissioning sites might be necessary. An NMVO should be prepared to support help these new End Users be technically ready for

decommissioning. Particular attention should be paid to software and scanner issues to avoid unnecessary alerts. NMVOs should actively share experiences with other NMVOs to avoid the same issues in countries.

- Covid-19 vaccine packs will include multiple doses. End Users should be reminded that a pack should only be decommissioned when the pack is first opened. Decommissioning multiple times will cause unnecessary alerts.
- End Users should be encouraged to verify a sample of packs at reception of products. This could help detect any data issues. This practice is already in place for many wholesalers. If data issues are encountered, the End User should contact the MAH/OBP directly to alert them of a problem.
- NMVSs have different configuration for how many times a pack can be scanned at the same location before triggering an alert. However, for IMTs there is no such leniency. Double scan at the same location will raise an alert. It´s important to make end-users aware of this and communicate clearly NOT to try to decommission a COVID19-vaccine pack twice. They should exercise accuracy and patience and to expect the reply from the system to take a little bit more time to get through than usual.
- If needed and not covered by existing practices, NMVOs should consider setting up a hotline to deal strictly with Covid-19 vaccine alerts. Details, e.g., availability times should be considered on a national level. Setting up a dedicated SPOC for Covid-19 vaccine alerts has also been recommended to the OBPs. This would help speed up the resolution of the alerts and is critical to ensure that no vaccines go to waste while feedback on an alert is awaited.
- As most of the vaccine pack data will not be uploaded to all NMVSs, some alerts will be triggered by IMT. Independently of the alerts being triggered by a local or IMT transaction, the originating NMVO where the pack is scanned is responsible for the alert investigation as they will have the end-user details and the pack is in their country. The NMVO that fulfilled the request (i.e., the NMVO in whose system the alert was generated) will generally only be required to collaborate in case of A7 and A24 alerts to provide whatever minimum amount of information is required from the audit trail to facilitate the alert investigation by the originating NMVO. Please see additional white paper on IMT alerts here.
- *ONLY FOR THOSE MARKET RECEIVING THE DATA.* There is a possibility that EMVO will inform the data receiving markets when the initial batches of vaccine data are loaded and the details associated with each batch. If this information is provided, we request that each data receiving market confirms receipt of the batch and the provided volume of packs as a manual measure to ensure that the data has been fully received and simple errors can be avoided.