Dear all,

In the Letter of Announcement from 26th September, EMVO recommended that wholesalers verify one pack per batch (released after 9th February) upon receipt.

EMVO would like to stress that this recommendation does not change the requirements set out in the Delegated Regulation (EU) 2016/161; and that verifications of all packs should be carried out in circumstances where mandatory verifications are required by law.

EMVO does, however, recommend verifying, on a voluntary basis and at the discretion of each wholesaler, one pack per batch received from the MAH, the original pack manufacturer or its designated wholesaler.

There was some confusion as to the requirements of the wholesaler following the Letter of Announcement from 26th September. EMVO would like to make it clear that the Letter of Announcement does not release the wholesaler from their legal obligations and that there are no changes to the legal requirements.

For further information, please consult the document titled ‘Guideline for EMVO and NMVO stakeholders: recommendations for alert handling and prevention process’ which is published in the Documents Overview of the Knowledge Database on the EMVO website.

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

Tel. Helpdesk: +372 611 90 44

E-Mail: helpdesk@emvo-medicines.eu

EMVO Team

European Medicines Verification Organisation

www.emvo-medicines.eu
helpdesk@emvo-medicines.eu

EMVO © 2019. All rights reserved.