MaMVO
Malta Medicines Verification Organisation

MaMVO Statement

The Pharmaceutical Supply Chain in the Post-Stabilisation Period - Pharmacies

In February 2019, MaMVO acting on the recommendation of EMVO (European Medicines Verification Organization) and PGEU (Pharmaceutical Group of the European Union) proposed a soft launching of the implementation of the Delegated Regulation on Safety Features, including a stabilization period of six months, in order to ensure an uninterrupted supply of medicines throughout the Pharmaceutical supply chain. The objective of this transition phase was to give users the opportunity to work with, and familiarise themselves with the system, while identifying and solving potential problems. During this period, pharmacies continued to dispense medicines, even in those cases where an alert was triggered, as long as there was no indication of falsification and as long as the medicines were purchased through the legal supply chain, as has always been the normal procedure. Similarly, wholesale dealers continued to transfer incoming newly-purchased stock, in accordance with existing procedures, unless there were overriding concerns that a falsified medicine was involved.

By notifying wholesale dealers of the end of the stabilization period on the 9 August 2019, MaMVO took a first positive step towards the achievement of the EMVS (European Medicines Verification System) objectives for which it was originally designed, in order to gradually stem the release of false positive alert-generating medicinal products into the pharmaceutical supply chain, whilst preserving the supply chain integrity, Simultaneously, MaMVO also extended the stabilization period for a further 6 month period for pharmacies, having noted the further recommendations of EMVO and PGEU regarding the significant need to reduce the generation of false alerts by end users, the causes of which continued to be multifactorial. Thus, in the interest of continuous supply to patients, MAMVO continued to allow pharmacies to dispense products which triggered 'false' alerts until the overall alert level stabilized to an acceptable low rate, according to EMVO recommendations.

MaMVO has actively monitored the situation throughout the past months, including, but not limited to, the rate of use of the system by end-users, and the generation and management of alerts. MaMVO has noted the gradual, yet steady decrease in the number of alerts, and in view of the current situation, is extending the current stabilisation period by a further three months.

It is MaMVO's opinion that, whilst the situation is subject to review at the end of this period, full implementation of the Delegated Regulation by moving towards higher implementation standards is an achievable goal within this time period. Pharmacies are therefore advised to systematically use the system as intended and undertake all the efforts within their remit/responsibility to diminish the number of 'false alerts', notably those generated by faulty scanners and IT system malfunctions, errors in manual input and the inappropriate use of bulk of pack verification and decommissioning.

MaMVO will continue to guide and support pharmacies in this respect, whilst working towards the implementation of an Alert Management System that will support all parties in best practices in the management of the few remaining alerts that may continue to be observed at the end of this period.

Nicholas Falzon
Chairman

Mary Ann Sant Fournier
Deputy Chair

Mario Debono
Treasurer

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