



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 stabilisation period of six months, in order to ensure an uninterrupted supply of medicines throughout the Pharmaceutical supply chain. 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. 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.

MaMVO 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.

By notifying wholesale dealers of the end of the stabilisation period on the 9 August 2019, MaMVO was moving positively towards the achievement of the EMVS (European Medicines Verification System) objectives for which it was originally designed if, whilst preserving the supply chain integrity, the release of false positive alert-generating medicinal products into the pharmaceutical supply chain is gradually eliminated.

On 9 August 2019, MaMVO also extended the stabilisation 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 cause of which continued to be multifactorial. In the absence of a stabilisation period, management of these alerts would have resulted in a shortfall of a substantial amount of medicinal products. 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 stabilised to an acceptable low rate, according to EMVO recommendations. In these circumstances, pharmacists still continued to dispense products triggering these alerts. However, all pharmacies were advised to systematically use the system as intended and undertake all the efforts within their remit/responsibility to diminish the number of 'false alerts'.

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On 9 February 2020, MaMVO advised that the stabilisation period for Pharmacies was extended by a further three months.

However MaMVO stated that Pharmacies were to take advantage of this extended stabilisation period to move towards higher implementation standards, such that there would have been a gradual progression towards post stabilisation.

Pharmacies were urged to credibly diminish alerts generated by faulty scanners, inappropriate use of bulk of pack and mistakes in manual input.

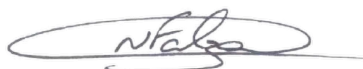
MaMVO continued to guide and support pharmacies in this respect.

The extension of the stabilisation period coincided with the unprecedented onset of the COVID-19 emergency which placed pharmacies on the frontline provision of a continuous essential health care service.

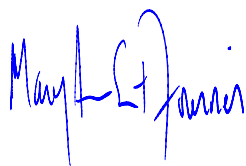
MaMVO, conscious of this serious contingency and in support of pharmacies, and to ensure the continuous access of medicines to patients, notifies an extension of the stabilisation period of a further six months, from 9 May 2020.

During this period pharmacies are urged to continue scanning whilst taking appropriate measures to decrease alerts which are end-user generated as explained above, and taking the necessary actions to attempt to successfully authenticate packs that fail to be authenticated correctly due to scanner or software issues.

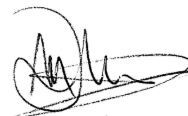
MaMVO will continue to monitor the situation, support pharmacies and shall review the position at the end of the forthcoming 6-month period.



Nicholas Falzon
Chairman



Mary Ann Sant Fournier
Deputy Chair



Mario Debono
Treasurer

11 July 2020