

## 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 Organisation) 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 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.

By recently notifying that it would not be renewing the above recommendations with regards to wholesale dealers when the stabilisation period ends on the 8th 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.

MaMVO, however, also notes the further, more recent, recommendations of EMVO and PGEU regarding the continued need to significantly reduce the generation of 'false' alerts, the causes of which are multifactorial, before an end to the 'stabilisation periods' can be declared. Until this point is reached, in the interest of continuous supply to patients, MaMVO recommends that pharmacies continue to dispense products which trigger 'false' alerts until the overall alert level has stabilised to an acceptably low rate, according to EMVO recommendations.

MaMVO, however, also concurs with the EMVO observation that for this decrease to happen, all wholesale dealers and pharmacies need to connect and systematically use the system as intended and undertake all the efforts within their remit/responsibility to diminish the number of 'false alerts'.

In view of the above, **MaMVO advises that its recommendations for a stabilisation period at Pharmacy level are hereby being extended by a further six months.**



**Nicholas Falzon**  
Chairman



**Mary Ann Sant Fournier**  
Deputy Chair



**Mario Debono**  
Treasurer

**8<sup>th</sup> August 2019**