

## MaMVO Statement

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

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 has been 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 normal procedure. Similarly, wholesale dealers continued to transfer incoming newly-purchased products to saleable stock, in accordance with existing procedures, unless there were over-riding 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. It is the opinion of MaMVO that, moving forwards, the European Medicines Verification System can only hope to achieve the objectives for which it was originally designed if, whilst preserving supply chain integrity, the release of false positive alert-generating medicinal products into the pharmaceutical supply chain is gradually eliminated.

In view of the above, MaMVO advises that **it will not be renewing the above recommendations with regards to wholesale dealers when the stabilisation period ends on the 8<sup>th</sup> August 2019.**

MaMVO's position in regards to alerts generated at pharmacy level will be communicated in due course.



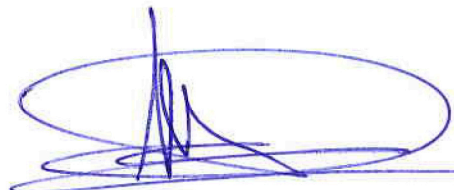
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**21<sup>st</sup> June 2019**