

MaMVO Statement

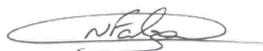
The Pharmaceutical Supply Chain in the Post-Stabilisation Period – Pharmacies

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. Subsequently, on the 9 August 2019, MaMVO notified wholesale dealers of the end of the stabilisation period, while extending the stabilisation period for a further 6 months for pharmacies. This in view of the further recommendations of EMVO and PGEU regarding the significant need to reduce the generation of false alerts by end users, in order to ensure that management of these elevated numbers of false alerts would not have a negative impact on the availability of medicines. The stabilisation period for pharmacies was extended by two further 6-month periods, on 9 February 2020 and 9 May 2020, in order to support pharmacies at the frontline in the provision of an uninterrupted healthcare service, during the unprecedented COVID-19 emergency.

In view of the continued healthcare challenge posed by COVID-19, as well as the uncertainty surrounding the Brexit process, MaMVO notifies that the stabilisation period for pharmacies is being **extended for a further 3 months from 9 November 2020.**

MaMVO specifies that the recommendations of the stabilisation period are not applicable to alerts which are end-user generated and in respect of which the pharmacist is easily able to take alternative or corrective action. These include alerts raised due to faulty scanners, inappropriate use of bulk of pack, mistakes in manual input, and mistakenly scanning in “CAPS LOCK” mode. Indeed, MaMVO points out that failure to take the necessary action and subsequently re-attempting to verify or decommission the pack, can lead to the authenticity of the correct pack data encoded in the Data Matrix not having been verified by the pharmacist, and furthermore result in the pack being left in an ‘Active’ state, when dispensed or otherwise decommissioned.

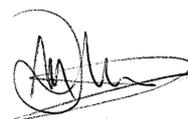
MaMVO therefore reiterates that pharmacies are to take advantage of this extended stabilisation period to move towards higher implementation standards, such that there would be a gradual progression towards post stabilisation. MaMVO shall continue to monitor the situation, and to guide and support pharmacies in this respect, and shall review the situation at the end of the forthcoming 3-month period.



Nicholas Falzon
Chairman



Mary Ann Sant Fournier
Deputy Chair



Mario Debono
Treasurer

7 November 2020