LETTER OF ANNOUNCEMENT

The Malta Medicines Verification Organisation is LIVE

23rd January 2019

Dear FMD Stakeholders

We are very pleased to announce that the Malta Medicines Verification System (MaMVS) is now connected to the EU Hub within the Live Production environment.

This major milestone would not have been achieved without commitment and effort from the MaMVO Project Management Team, and continuous guidance and support from the MaMVO Board and all the stakeholders in the Maltese medicines supply chain involved in the implementation of the Falsified Medicines Directive in Malta. We also acknowledge the valuable support received from the EMVO team during the MaMVO onboarding process, all the work done by our blueprint software provider, Solidsoft Reply, and the collaboration established with the other NMVOs.

The MaMVO will now conduct a controlled and limited first use of the Production Environment as part of a closed Pilot with a selected group of pharmacies, wholesalers, manufacturers and IT software providers. We therefore strongly encourage Marketing Authorisation Holders (MAHs) to start uploading serialised pack data to the MaMVS through your OBPs to the EU Hub, for packs that have been released for the Maltese market. A retrospective upload to the Maltese repository will need to take place for multi-market packs which have already been uploaded into other countries.

We will also be focusing on the end-user onboarding process enabling pharmacies, health service locations and wholesalers holding a valid licence in Malta to connect to the national system, the MaMVS, in readiness for FMD regulatory go-live on the 9th February 2019. Details of the end-user onboarding process may be found on https://www.mamvo.org/on-boarding/endusers/

We thank the many MAHs who have completed the MaMVO MAH onboarding process. For those who have not yet done so, please visit https://www.mamvo.org/on-boarding/mahs/ for all details. Registration details for 2019 will soon be available.

For any further information about the MaMVO, please visit our web portal www.mamvo.org or contact us by email on info@mamvo.org. We will be more than happy to answer any questions on the implementation of the FMD in Malta.

Kind regards,

[Signature]

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