LETTER OF ANNOUNCEMENT
EU Hub Alert on the Randomisation of serial numbers

Wednesday, the 8th of August 2018

Dear On-boarding Partner,

The purpose of this letter is to provide you with further information and guidance regarding the upload of 'serial numbers' of your products to the EU Hub.

The 'serial number' is part of the unique identifier which is placed on the outer packaging of a medicinal product and must be created according to the specific randomisation rules detailed in the Delegated Regulation (DR). Recently, several On-boarding Partners (OBPs) reported that they received the following 'warning message' related to the randomisation of serial numbers:

#A54 Insufficient Randomisation of Serial Numbers

Please be aware that the 'warning message' does not stand for the 'blocking error message'. EMVO wants to assure you that, when the 'warning message' is received, the serial number data is still distributed to the various national systems. Nevertheless, EMVO stays open and listening to your feedback and will review the randomisation checking alert mechanism applied.

In the meantime, EMVO requests all OBPs to continue to generate 'serial numbers' according to the specific randomisation requirements and **continue to upload the data in the EU Hub**. The warning is triggered for informational purposes only and does not block the OBP from loading the data into the EU Hub.

In order to assist you in the most efficient way, please find below the requirements related to the randomisation according to the Falsified Medicine Directive (FMD) and the Delegated Regulation:

- a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm ('serial number')
- the probability that the serial number can be guessed shall be negligible and in any case lower than one in ten thousand

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

Tel. Helpdesk: +372 611 90 44

E-Mail: helpdesk@emvo-medicines.eu

EMVO Team

European Medicines Verification Organisation

www.emvo-medicines.eu

helpdesk@emvo-medicines.eu