

OSMR Newsletter 03/2018 – December 21st

We are getting closer to the project **Go-Live – February 9th, 2019**, only 30 working days left until the FMD comes into force, until the initiative to ensure patient safety by preventing the entry of falsified medicinal products into the legal supply chain becomes a reality.

Great effort has been put into this one-of-a kind endeavor by all stakeholders. However, there are still many things to be done in order to reach a level of preparedness of the pharmaceutical industry.

MAH Companies and their potential On-boarding Partners (OBPs) have started to upload pack data destined for the Romanian market to the EU Hub, enabling thus data availability in order to undergo the **PILOT phase, scheduled to end on January 15th, 2019**.

End Users are in the process of registering in the National Medicines Verification System, some of them participating in the PILOT phase tests.

Please visit our new website section for more **details on the enrollment status in NMVS:** [enrollment status details](#)

As it can be seen on the graphs from the above mentioned section, a relatively small number of End Users have registered considering the time left until the project go-live, therefore please see our kind request for speeding up the submission of the Participation Request Form: [End User's Registration](#).

Please mind that the registration process takes approximately one week, however this period will increase if many End Users apply for registration on the last weeks before February 9th, 2019.

One topic which needs to be clarified is related to the authorization transfer between MAHs and how this is reflected in the affiliation process to OSMR.

Therefore, if an authorization is transferred from one MAH to another, and the new MAH is already an OSMR affiliated member, then there is no need for the affiliation process to be started, consequently no need for a new affiliation fee to be paid. The only documents required are the ones stating the transfer.

However, if this is not the case, then the new MAH must apply for OSMR membership and make the payment of the affiliation and membership fee.

The obligations chapter of an OSMR affiliated member has been updated and can be found in the **Association's Bylaws** ([Association Bylaws](#)) which you are kindly advised to consult.

Also, please be reminded that the Order of the Ministry of Health that has been published in Monitorul Oficial on December 5th 2018 contains the **detailed rules for the safety elements which appear on the packaging of the medicinal products for human use** ([Ordin MS](#)).

OSMR Team wishes you a wonderful holiday season and warm wishes for 2019!

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