

DOCUMENT NUMBER

04-2/2019-2

LOCATION, DATE

Ljubljana, 29.1.2019

SUBJECT

Letter to Marketing Authorization Holders regarding data upload in the Safety Features repository system (SiMVS)

In order to comply with the Falsified Medicines Directive 2011/62/EU and Delegated Regulation (EU) 2016/161, marketing authorization holders (MAHs) are responsible for ensuring that medicines marketed in the EU carry the safety features (UI and ATD) from 9th of February 2019. MAHs must also ensure that the data contained on the Unique Identifiers is uploaded in the repository system to enable mandatory verification and deactivation of medicines by pharmacists after 9th of February 2019.

We received information that pharmacists are unable to verify and decommission medicinal products due to the missing data in the repository system. Another common technical issue that occurs during verification is caused by the data inconsistency in the system. In order to ensure positive response during verification procedure, the expiration date format on the pack (in the Data Matrix barcode) must be identical to the information loaded into EMVS. For example: *EXP: 230400* and *EXP: 230430*, both mean April 30th 2023, but from the NMVS perspective, *230400* is not equal to *230430*, so an alert is triggered.

With this letter, we are urging MAHs to:

- **upload the missing data in the system for all medicinal products that have been already released for sale and distribution with Unique Identifiers in the 2D Data Matrix barcode and to**
- **ensure that any data inconsistency issues are fixed before 9th of February 2019.**

Please note that all verifications of Unique Identifiers not uploaded in the system will generate a potential falsification alert after 9th of February 2019, which might lead to disruptions in the supply chain.

Therefore, and taking into consideration that from 9th of February 2019, dispensing of medicines requires mandatory verification and decommissioning of the UIs by pharmacists, **MAHs and OBPs must ensure that the data uploaded in the repository system is accurate** to avoid any potential falsification alerts and thus, actions by National Competent Authority (JAZMP) after that date.

With kind regards,



Momir Radulović

Director