

10th July 2019

EMVO stakeholders¹ consideration on enforcement and inspections under the Falsified Medicines Directive 2011/62/EU (FMD) and its Delegated Regulation EU 2016/161 (DR)

EMVO stakeholders would like to encourage the National Competent Authorities to start enforcing the primary requirements of the FMD and DR and undertake inspections on all supply chain actors. Both EMVO and NMVOs stand ready to supply all necessary and available information to National Competent Authorities.

1- Situational assessment:

5 months into the operational phase of the European Medicines Verification System (i.e. after the 9 February 2019 implementation deadline) a significant number of manufacturers and supply chain actors have not yet connected to the system. Current available data from EMVO/NMVOs estimate that two fifths (40%) of manufacturers as well as one quarter (25%) of other supply chain actors (pharmacies, hospitals, wholesalers, dispensing doctors etc.) have not yet connected to the medicines verification system(s).

At the same time, approximately 3% of all scans undertaken by supply chain stakeholders lead to a 'false alert' being generated due to various reasons (and, most of the time, a combination of reasons), such as: missing data upload into the European Hub, incorrect data upload, incorrect scanner configuration of end-users, pharmacy/hospital software systems not updated, procedural reasons, system not used properly etc.

2- EMVO stakeholders' activities and limitations:

EMVO stakeholders have continuously reached out to their members and individual supply chain actors across Europe to inform them about the FMD and the requirements of the DR, as well as their individual responsibilities in the new paradigm. This has been done through educational campaigns, development of information materials, technical briefings, workshops, meetings with members, newsletters, websites etc.

Despite all the best efforts, the EMVO stakeholders do not have a 100% coverage of all individual supply chain actors impacted by the FMD. More importantly, EMVO stakeholders are not-for-profit associations representing the interest of their members, they do not have enforcement powers to compel supply chain actors to abide by their regulatory requirements.

Notwithstanding these limitations, the majority of supply chain actors have connected to the medicines verification system and have diligently worked to upgrade their systems and processes. Currently, they are in operational mode, which includes responding to this high level of 'false' alerts to the best of their ability.

¹ The term 'EMVO stakeholders' in this document covers EMVO's full member organisations EAEPC, EFPIA, GIRP, Medicines for Europe and PGEU.

10th July 2019

3- Call for a stepwise/phased approach to enforcement and inspections by National Competent Authorities

As such, the EMVO stakeholders would like to encourage the National Competent Authorities (NCAs) to start enforcing the primary requirements of the FMD and DR and undertake inspections on all supply chain actors.

In the interest of achieving the desired outcome, they consider important to focus compliance efforts where they will achieve most effect:

3.1 Full IT stabilization of the system(s)

The European Medicines Verification System (EU Hub and National Systems) needs to be fully stabilized from an IT point of view and provide the full range of functionality in order to provide a trusted environment for all supply chain stakeholders to connect to the system.

3.2 Supply chain actors who are not connected to the system at all

The system can only fully work as intended if all actors are connected to it. 'Stabilization periods' allow currently connected supply chain actors to 'use & learn' the system in each market. Squandering this opportunity means that technical, IT, procedural problems will lead to an actual impact on patient access to medicines. Liability is also engaged for actors who do not use the system at all.

3.3 End-user IT software providers

A number of end-users experience a significant delay in upgrading their software to comply with the coding/decoding rules of the verification system. Further, IT software provided to some end-users has 'bugs' or configuration errors. As such, a significant number of 'false' alerts are generated by IT systems 'misreading' the 2D matrix code at end-user level.

3.4 Manufacturers connected but not uploading data

Releasing serialized medicinal products on the market without uploading the corresponding data into the verification system(s) leads to 'false' alerts being generated for each individual medicinal product.

3.5 End-users connected but without configuring scanners, establishing procedures and/or proper training for staff

Each discrepancy in the data read on the pack and verified against the data stored in the national system leads to a 'false' alert. Sometimes, this can be caused by improper configuration of scanner. Other times, staff interacting with the system multiple times with the same pack leads to 'false' alerts due to lack of procedure and/or proper training.

3.6 End-users connected but not scanning serialized packs

Dispensing serialized packs to patients without verification/decommissioning poses a security risk. Any criminal actor could make use of the discarded packaging (i.e. copy the 2D matrix on a fake pack) and re-introduce falsified medicines into the supply chain. Unfortunately, and unacceptably, in such a case they will pass a verification/decommissioning activity due to the fact that the Unique Identifier remains active in the system.

10th July 2019

4- Information sources:

EMVO has the full overview of manufacturers which have connected to the EU Hub and is publishing the list on its website <https://emvo-medicines.eu/pharmaceutical-companies/connected-companies/>.

NMVOs have granular information regarding the situation within their market concerning which end users have not yet connected, which end-user IT software providers have not upgraded their system to comply with the coding & decoding rules of the new system, which end-users are connecting but are not scanning serialized packs, and also, at the same time, which manufacturers are consistently releasing serialized medicines in their market, without uploading the corresponding data into the respective NMVS.

Both EMVO and NMVOs stand ready to supply all necessary and available information to National Competent Authorities.

5- Reports for National Competent Authorities (Art. 39 of the DR)

EMVO stakeholders are disappointed that the provision of reports for the NCAs to access the data within the system for the purposes outlined in Article 39 of the DR have been delayed to this extent. It is without a doubt that the reports to be provided by EMVO/NMVOs will significantly empower NCAs to supervise the system.

Despite this situation, EMVO stakeholders believe that there is still significant scope for NCAs to use their regulatory enforcement powers towards the supply chain stakeholders, as outlined above. Data from the EMVO/NMVOs can be used to establish a risk map of the supply chain and focus enforcement efforts. EMVO stakeholders continue to believe in the power of 'traditional' on-site inspections to enforce compliance on supply chain actors.

6- Towards an end of 'stabilization periods':

EMVO stakeholders consider that they can only credibly create an environment where National Competent Authorities can declare an end of the 'stabilization periods' if the number of 'false' alerts is significantly decreased (at least 100-fold reduction).

Until this point is reached, products which are triggering 'false' alerts should still be dispensed to the patient and not be returned upstream in the supply chain, since the causes of these 'false' alerts are multifactorial. With a 'false' alert rate of 3%, this might lead to up to 2,000 products being in short supply. In the interest of continuous supply to patients, EMVO stakeholders suggest allowing end-users to dispense products which trigger 'false' alerts until the overall alert level has stabilized below 0,05%.

However, for this to happen, all supply chain actors need to connect and systematically use the system as intended and undertake all the efforts within their remit/responsibility to diminish the number of 'false alerts'.

Without this, the EMVO stakeholders consider there is a significant risk towards descending into a downward spiral in which alert levels remain high, so stabilization periods are extended, removing the pressure for improved compliance, and resulting in persistent high levels of 'false' alerts. Needless to



10th July 2019

mention, such a breakdown will lead to a dysfunctional system, wasted investment, reduced trust and confidence especially for patients, who should be the main beneficiaries of this effort.

7- Continued commitment to safe medicines but also to patient access

EMVO stakeholders remain committed to provide access to safe medicines to patients in Europe. They believe the new medicines verification system strengthens an already safe supply chain and they wish to rapidly achieve a return to business-as-usual where all supply chain actors use the system as intended to prevent any falsified products penetrating the EU legal supply chain.

To achieve this objective, EMVO stakeholders would like to encourage the National Competent Authorities to start enforcing the primary requirements of the FMD and DR and undertake inspections on all supply chain actors. Both EMVO and NMVOs stand ready to supply all necessary and available information to National Competent Authorities.

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