PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PGEU statement on the potential use of the data contained in the EMVS to monitor shortages

In the context of the ongoing discussions on how to address medicines shortages at EU level, the use of the data contained in the European Medicines Verification System (EMVS) has been brought up as a possible way for monitoring shortages.

In this statement, PGEU outlines why the EMVS is not an appropriate and effective tool to monitor shortages in the pharmaceutical supply chain, in light of the legal and technical limitations of the system.

1. Background

The European Medicines Verification System (EMVS) has been set up and managed in accordance with the Falsified Medicines Directive (FMD) 2011/62/EU and its Delegated Regulation (DR) 2016/161/EU laying down detailed rules on the safety features of medicinal products.

The European Medicines Verification Organisation (EMVO), of which PGEU is a founding member, is the non-profit organisation representing stakeholders united in securing the legal supply chain from falsified medicines. EMVO is responsible for the advancing the formation of the EMVS.

PGEU, along with other supply chain stakeholders within EMVO, has been working on implementing the provisions of the FMD and of its DR. PGEU and its members across Europe have supported the realization of the EMVS with the objective to consolidate the barriers that prevent the entry of falsified medicines into the legal supply chain. As of 9th February 2019, the EMVS went live across Europe. With this system in place, right before dispensing a medicine to the patient, the community pharmacist verifies the safety features on the medicine pack and decommission its unique identifier from the system. In this way, community pharmacists perform a final safety measure to ensure the end point verification of the medicine's authenticity.

2. Description of the functioning of the EMVS

The EMVS is a system enabling end-to-end verification of (mostly) prescription medicines, designed to uphold patient safety by preventing falsified medicines from entering the legal supply chain.

The EMVS was put in place – under the mandate of the Falsified Medicines Directive (Directive 2011/62/EU) and the associated Delegated Regulation (EU/2016/161)—to be a secure, interoperable, and cost-effective system across Europe.

The functioning of the EMVS is described in a nutshell as follows:

- Pharmaceutical companies intending to distribute medicines within the EEA must become contractual On-Boarding Partners (OBPs) with EMVO. This is performed via the EU Hub: a centralised database and router that stores key information about the manufacturers (or parallel distributors) and their products.
- The OBP connects and uploads data to the EU Hub on behalf of the European Marketing Authorisation Holder(s) (MAHs); affiliated companies to the OBP holding the licenses to market and distribute medicines in the EU and European Economic Area.
- The OBP uploads Product Master and Batch Data—including a Unique Identifier (UI) code, expiry date, batch, and serial numbers for every pack—into the EU Hub. These UIs are distributed to national systems across 30 countries within Europe.

- National Medicines Verification Organisations (NMVOs) manage these national systems that use this information to ensure that products can be verified and decommissioned by end-users (pharmacies, hospitals, wholesales (under the limits of the legislation) and other persons authorised to supply medicines to the public).
- National Competent Authorities (NCAs) interact with the EMVS within the context of their right to access data as established in Article 39 of the DR and the framework of the reports established for this purpose.

3. Legal and technical limitations

There are several reasons why the EMVS is not fit for monitoring shortages of medicines.

Firstly, the FMD legislation does not foresee to use the EMVS to monitor shortages. Furthermore, it should be noted that there are legal limitations to data access in the EMVS, even for the NCAs as set out in the legislation. As outlined in Article 39 of the DR, NCAs can only access data contained in the repository system of their Member State for the following purposes: (a) supervising the functioning of the repositories and investigating potential incidents of falsification; (b) reimbursement; (c) pharmacovigilance or pharmacoepidemiology. Whenever NCAs need to access data for these purposes, they do so via pre-defined reports issued by the system.

From a more technical point of view, the EMVS is designed as an ''end-to-end'' verification system and not as a ''track and trace''; as such, it is not possible to track a single product along the supply chain.

In addition, there are more technical reasons on why the EMVS is not designed for monitoring shortages. Most importantly, the system does not include any actual stock level data. As not all packs for which data are uploaded in the EMVS are ultimately decommissioned, the EMVS cannot provide a reliable indication on the stock levels in different parts of the supply chain. This is due, for instance, to the presence of multi-market packs, whose data are uploaded by OBPs in all potential destination markets and therefore counted multiple times without being actually available in these markets. Moreover, a percentage of products is removed from the market by pharmaceutical companies for testing purposes, but their data are included in the EMVS.

As the system contains data on many products that, for these and other reasons, do not reach the destination market, the current level of uploaded master data in the EMVS does not reflect the actual available stock levels in the Member States. This means that the data stored in the EMVS would lead to an overestimation of the availability of medicines in Europe.

When it comes to data generated at end-user level, the number of decommissioned packs available in a Member State territory is available to the NCA. However, such data do not reflect the actual demand for a given medicinal product, especially since products that are unavailable or otherwise short in supply cannot be decommissioned. In addition, in some cases, packs are decommissioned before being delivered to the people authorized to supply to the public (e.g. dispensing doctors in some countries) or already at the point of entry (e.g. in healthcare institutions). In these cases, the EMVS database does not account whether the pack has been actually dispensed to a patient or just to the person authorized to supply, as it only registers the decommissioning of the pack.

Furthermore, decommissioning data would not be able to take into account changes in demand for medicinal products due to unforeseen patient needs (e.g. in relation to the Covid-19 pandemic).

4. Conclusion

Community pharmacies are committed to support the competent authorities in managing shortages. To this end, it is necessary to promote the interoperability of different national reporting systems for shortages already in place in several EU Member States, as well as a harmonization of the concepts and the criteria for reporting of shortages.

PGEU considers that a combination of real-time stock level data in the medicine supply chain with dynamic and accurate data on patient demand could assist authorities to forecast potential supply disruptions and inform needed actions and policies. At the same time, in view of the legal and technical limitations outlined above, PGEU considers that the EMVS, as it is designed, is not an appropriate and reliable tool to monitor shortages of medicines.