EMVS Stabilisation Period – Recommendations

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2. Introduction

The European Medicines Verification System (EMVS) is a truly transformative project, and one which is unique in its stakeholder-led model. The start of the Operational Phase of the EMVS on February 9th is the culmination of several years' work by the stakeholders of the pharmaceutical supply chain, with all work being aimed strengthening the security of the supply chain against the potential entry of falsified medicines.

However, with a project of this size, and one that is being implemented from the ground-up, there are likely to be teething problems in the initial period of the Operational Phase. To address this and to ensure that there are as few as possible disruptions in the supply chain, EMVO promotes a so called Stabilisation Period; which would be a soft launch working on a case by case or market by market approach. This approach will ensure the stable uptake of each National Medicines Verification System (NMVS) and will ensure an uninterrupted medicines supply throughout the whole supply chain. During this so-called Stabilisation Period, certain system alerts caused, inter alia, by missing or incorrectly uploaded data, scanning products not in the scope of FMD, scanning so called 'Indian packs', procedural mistakes at

wholesale/pharmacy level leading to 'pack status error' alerts, etc. should not be considered as indicative of a potential falsification by End-Users[1] but will nonetheless be visible to them, the NMVS and the NCAs.

For the avoidance of doubt, and as part of EMVO's recommendation, medicines should still be checked by the entity supplying medicines to the public and reported to the authorities, as managed before the Operational Phase from 9th February 2019.

3. Why is a Stabilisation Period needed?

In the first instance, and in a purely practical sense, the EMVS is a European-wide IT project. operating across the EU and EEA. Its technical establishment is a real and tangible achievement. The fact that the EMVS has been successfully established on time is remarkable when it is considered that the system is comprised of 29 national systems connecting, over 1000 OBPs (connecting over 1,500 manufacturers and parallel distributors) via the EU Hub, and over 150,000 End-Users which are all connected at national level.

The fact that national systems became operational less than 1 year before the deadline and that most manufacturers and End-Users only recently connected to the system has left little time at everybody's disposal to properly test their connection and get accustomed to using the system overall as well as iron out the inevitable technical bugs and overcome the procedural learning curve.

Indeed, the interoperating of the system has only recently started, and the stabilisation of the system is ongoing. That this period of stabilisation is required is clear when one considers that the National Systems and the EU Hub have only recently reached a level of maturity which is necessary to comply with the Delegated Regulation.

We already identified some challenges which will be faced by the EMVS during the initial period after February 9th. For instance, a number of OBPs are using inconsistent date formats for the expiration date printed on the Data Matrix code and the expiration date uploaded into the EMVS. At the same time certain IT systems (used either by OBPs or End-Users) are automatically 'translating' the expiry date due to their technical inability to 'read' 00 as a data input field. End-Users will also face a particular challenge in identifying the so called 'Indian packs' which are manufactured in India and have been serialized according to the Indian export serialization requirements using a similar 2D Data Matrix code. It is visible today that 'Indian packs' released on the EU market before the 9th February 2019 do not have their corresponding data uploaded into the system.

In addition to this, it is envisaged that there is an issue related to missing call-backs from the EMVS. For transactions, such as data upload, the EMVS sends back a confirmation message which would indicate that data is valid, loaded and distributed. However, due to a technical misconfiguration these call-back messages are not always being sent. As such, manufacturers do not have absolute certainty that their data has been successfully uploaded in the respective national system and may be forced to undertake a verification of 1 pack of those batches (Single Market Packs only) or re -upload the batch (Multi-market packs only) in the respective system, thus increasing the overall workload on the system.

These, and other examples, adds further weight to the case for a period of stabilisation.

[1] End User shall mean any wholesaler, pharmacy or other person authorized or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation

a. Alert Handling

The ultimate goal of the EMVS is to ensure that falsified medicines are kept out of the legal supply chain and ultimately do not reach the patient. The system is designed to trigger an alert, if a verification/decommissioning event reveals a suspicion that the product is falsified. However, the current expectation is that the number of alerts triggered by the EMVS will in no way reflect the number of falsified products, as alerts may be generated by technical or procedural mistakes. A high number of alerts may lead to a disruption of the distribution of medicines if the Delegated Regulation (DR) is followed to its full extent immediately from the 9th of February 2019.

Therefore, under Stabilisation Period, it is proposed that there would be a policy of flexible alert handling until the system is properly stabilised. This is in order to avoid unnecessary disruption to the supply chain.

In addition to the proposal on alert handling, EMVO suggests a series of initial preventative measures on alert handling to avoid any potential supply disruptions due to the full operation of the verification system:

a) Manufacturers would verify at least one pack per batch before release, including the Anti-Tampering Device.
b) Wholesalers would verify at least one pack from each batch. If there is an alert, a deviation investigation would be initiated. In this case, the batch in question would be transferred to saleable stock if the wholesaler has no doubt about the authenticity of the product.
c) To prevent level 5 alerts, a downgrading would take place for unknown product codes, missing batch data and expiry date mismatch.

EMVO stakeholders have worked together to devise practical guidelines to prevent alerts being generated in the first place (due to technical or procedural mistake) as well as to handle the alerts generated nonetheless. The Stabilisation Period acknowledges that investigative actions may not be as effective nor as fast as needed to cope with the initially expected number of alerts, therefore supply chain actors should prioritise access to medicines for patients. However, the Stabilisation Period should be viewed as a waiver of ends, not of means. That is to say that all individual stakeholders need to make an effort and investigate the alerts in the system, but should the investigation not be successful patients should not be denied access to their medicines.

This proposal on alert handling is one which already reflects discussions internally within several participating countries, where flexible alert management is being taken alongside a set period where NCAs will not be imposing fines.

b. Serialisation

An additional factor to consider is that in any case there will be a period of several years in which serialized and non-serialized packs will be on the market and being dispensed to patients. This is combined with the fact that 10%-20% of packs are yet to be serialised. This phasing in of serialisation, and the time taken from the beginning of the Operational Phase to the point at which all packs in-scope are serialised would lend itself to the conclusion that in any case a Stabilisation Period is taking place.

c. User Compliance and Enforcement

It is anticipated that during the initial period of the Operational Phase, there will be a period in which enforcement by National Competent Authorities is handled in a flexible manner. This is recognition of the fact that the system is new and that some end users in some participating countries are not yet ready for the Operational Phase. Indeed, it has been suggested that some NCAs will not enforce fines for a specific period of time from February 2019 in order to provide End-Users with a "grace" period to connect to the system as soon as possible or to become accustomed to the EMVS. This is a key component of the Stabilisation Period being proposed by EMVO and which some participating countries have already embraced.

4. What would the Stabilisation Period look like?

During the Stabilisation Period advocated for by EMVO:

1. All pharmaceutical companies and parallel distributors placing medicinal products into your market have a connection via their OBP with the EU Hub and upload their Product Master Data (PMD) and Product Pack Data (PPD) into your NMVS in accordance with the Delegated Regulation.
2. All End-Users are connected and are actively using your NMVS for verification and decommissioning activities, in accordance with the Delegated Regulation.
3. Medicines are not unreasonably withheld in the supply chain and from distribution to patients; unless clear indication is available that the pack is falsified.
4. Each NMVO monitors the status of the above points.

Usage of the system is of utmost importance as data on the functioning and effectiveness of the system will be collected. This data can be analysed and provide information on how the performance of each NMVS can be improved. Once this data is collected and analysed, corrective actions can take place. These will lead to an NMVS which filters out suspected falsified packs with a high degree of certainty without unnecessary obstruction of the supply of medicines.

a. Crisis Management

During the Stabilisation Period teething problems are to be anticipated and any technical issues arising should be addressed as soon as possible. In this spirit, a system of rapid crisis management is required to handle such issues during the Stabilisation Period.

This system of crisis management begins by detecting the crisis and EMVO coordinating the root cause analysis. Once these have been completed, and the cause has been identified, follow up actions will be completed to solve the crisis.

Throughout this process, EMVO will maintain a consistent line of communication through Letters of Announcement and the Downtime and Disruption Information System (DDIS). We will be transparent on our progress and will inform the relevant parties once issues have been solved.

5. What must be achieved before the end of the Stabilisation Period?

In order for this period of stabilisation to be judged a success, a combination of factors is required:

a. Well performing IT Systems

- ### EU Hub and NMVS

  At this moment the core European Medicines Verification System (which consists of the EU Hub and the NMVSs) is ready to meet the requirements of the Delegated Regulation (DR). One exception applies to the NCA reports which are still under development. These IT systems are under the responsibility of the EMVO and the NMVO's.

- ### IT systems of On-Boarding Partners (OBPs)

  All Marketing Authorisation Holders (MAHs) and parallel distributors are to be connected via their OBP to the EU Hub to load data in the EMVS. The IT systems which support the upload of data from the OBP to the EU Hub should meet the quality standards which have been defined in the System Development Kit (SDK) documentation. These IT systems are under the responsibility of the OBP's.

- ### IT systems of End-Users

  The IT systems of the End-Users need to connect securely to the NMVS while meeting the requirements of the EMVS. The NMVO should oversee the hard- and software readiness of IT systems supporting the wholesalers and the pharmacists. These IT systems are under the responsibility of the End-Users.

b. Trained End-Users

It is necessary that in the Stabilisation Period further training of On-boarding Partners and End-Users takes place and experience is gained on best practices.

With respect to OBPs; it is of utmost importance that all MAH's placing medicinal products in a market use the EMVS for its intended purpose. This can only be achieved when OBP's have sufficiently trained staff and are familiar with the EMVS procedures.

For End-Users training is even more critical. It is essential that all End-Users are connected and use the system for its intended purpose. The number of errors triggered by the system caused by unintended use is a good indicator of the End-User training level. Unintended can be understood to be examples such as the scanning of a pack more than once, or consistently scanning packs which are not subject to the DR.

When these goals are reached, the stabilisation period can be ended and all alerts can be treated as potential falsifications.

c. Ensured data quantity and data quality

In order to ensure that the necessary improvements to the system are made, and that repeat instances of the same issue do not occur, the availability of data is absolutely vital. Without the availability of reliable data, it is very difficult to work through any technical difficulties which may arise.

In ironing out the initial difficulties, and by collecting as much reliable data as possible, we can ensure that the end users will not be burdened in the future by an unnecessarily high number of alerts.

- To ensure data quantity:

  To avoid the system triggering unnecessary error messages, all packs which are physically in the market should be reflected by Product Pack Data in your NMVS.

- To ensure data quality:

  The Product Master Data (PMD)and Product Pack Data (PPD) available in your NMVS should meet the EMVS data quality requirements. Incorrect data may accidentally pass the data validation checks of manufacturers' internal systems, and subsequently may lead to false error messages and alerts.

d. Refined and Adjusted Procedures

As your NMVS is a complete new system, no large scale experience could yet be gained on its use and management. Procedures which are currently in place are expected to be refined and adjusted. Once the updated procedures are mature and embedded in the daily habits of NMVS users, the system will be perceived as stable.

6. An end to the Stabilisation Period

By September 2019 (i.e. roughly 8 months after the entry into force of the Delegated Regulation) EMVO, EMVO stakeholders and the European Commission (at EU level) and NMVOs, national stakeholders and National Competent Authorities (at national level) will undertake a thorough assessment of the status of stakeholder compliance with DR requirements as well as the status of overcoming the challenges identified in this paper. This assessment should end the Stabilisation Period enabling the return to 'business as usual' for all supply chain stakeholders as well as the proper investigation of all alerts generated by the system, with all the solemnity implied by the very generation of the respective alerts.

7. Conclusions and Recommendations

In short, EMVO's proposal for the Stabilisation Period from 9th February 2019 covers a period to ensure a controlled application of the NMVS and an uninterrupted medicines supply.

In the proposed Stabilisation Period there should be:

- Flexible alert handling;
- Enforcement and inspections only on a case by case (market by market) basis with a staged implementation of NCA reporting;
- Completion of serialization;
- Increase of EMVS stability/performance, i.e.
  - Well performing EU Hub and NMVS (data quantity & data quality of utmost importance)
  - Well performing IT systems of On-Boarding Partners (including trained OBPs)
  - Well performing IT systems of End-Users (including trained End-Users)
- Effective crisis management, which will maintain trust in the system's added value;

The EMVS is a completely new system. As such, no large-scale experience could yet be gained on its use and management. It is to be expected that procedures which are currently in place will need to be refined and adjusted. Once the updated procedures are mature and embedded in the daily habits of NMVS users, the system will be perceived as stable. This must be the responsibility of all of those involved in the operation of the EMVS, as we must ensure a stable verification system to meet our goal of enhancing patients' access to safe medicines.

From EMVO's discussions with the European Commission, it is clear that they are fully appreciative of the problems which will arise from implementing such a complex and interoperable system. Based upon this, the European Commission accept the concept of the Stabilisation Period as laid out in this document. In order to realise this proposal, specific and measurable indicators are needed to track progress during the Stabilisation Period, during which time the European Commission would liaise directly with National Competent Authorities on crisis management and stabilisation within each Member State.

Furthermore, the EMVS is a demanding but highly valuable project for all of those involved, and for patients across Europe. It is therefore vital that we maintain trust in the system and that its added value is recognised. It is therefore EMVOs recommendation that this Stabilisation Period is enacted in order to ensure that these aims are met.