

LETTER OF ANNOUNCEMENT
EMVS Known Issues

15th February 2019

Dear all,

EMVO is contacting you today as we wish to give you a full and comprehensive update on the current status of the EMVS.

Providing the most accurate and up to date information has been EMVO's priority in this period, and in the spirit of this aim we can lay out in detail the main challenges which are currently being faced by the EMVS.

EMVO's highest priority is to ensure that OBPs can upload data and that the system remains stable.

Therefore, the following list details the 3 top issues which are currently being faced by the EMVS:

1. Missing Call-backs

Lately some of the OBPs may have experienced that they did not receive a final response from the EMVS stating that data has been distributed successfully or not. These final responses would confirm that the serial numbers were correctly and fully uploaded into the national systems. OBPs may have received a missing call-back (from a national system).

OBPs may have only received an 'A17 distribution failed' message from the EU Hub after 24 hours, or in rare cases not at all. This message is issued when national system(s) have not confirmed to the EU Hub that the data was processed in the national systems (missing call-backs).

In case of a single market pack, if you did not receive a distribution call-back within 24 hours for a 'Product Pack Data Upload', 'Product Pack State Update', or 'Product Pack Verification', we recommend OBPs to perform a verification of one or more packs of the uploaded batch.

EMVO, the affected national systems and their providers are together investigating in full these issues. However, some root causes have already been identified and some fixes are envisaged to be implemented over the weekend.

The below table provides an overview of the call-backs received by OBPs:

| Call-back received by OBP | | No Call Back | |
|---|---|---|--|
| Within 24 hrs | | At 24 hrs | After 24 hrs |
| Positive | Negative | 'Missing Call-Back' A17 | No call back is ever received by OBP |
| A call-back is received to confirm that the data is uploaded well in the National System(s) | A call-back is received from the National System(s) to inform the OBP that something is wrong with the data | This means that the EU Hub did not receive / is missing a call-back from the National system within 24 hrs. | Known Issue: Product Pack Status update (PSUM) which will be repaired this week. + Further analysis ongoing |

2. Multi-market pack synchronisation issue

After a thorough investigation it has been concluded that because of the different implementation of multi-market pack sync, a loop was created within the EMVS. This caused full queues and a high load in the database, which reduced performance in the impacted markets. The root cause analysis has been completed and a fix is being defined.

A fix has been identified and it is planned to be implemented over the weekend by the affected Blueprint providers. Their current working estimate is that a resolution will be provided on Sunday 17th February.

3. EU Hub non-availability

Currently, it may be that a transaction attempt with the Hub is met with error message O1 – System Unavailable. This issue is being faced in the PRD environment.

If you experience this issue, and are met with error message O1, we advise that you re-do the action after approximately 1 hour.

On Thursday 14th February EMVO investigated the issue and implemented the first fixes to the issue. However, we are still investigating the root cause of this issue in cooperation with the IT provider and Microsoft. This issue has the highest priority.

Additional Known Issues

Further to our communications on the [EVI \(European Medicines Verification System Information\)](#), there are additional Known Issues which are affecting the EMVS at present. For full information related to each known issue, please consult the EVI.

EU Hub:

- Reconfiguration of Alerts.
- No emulated markets with 2018 schema.
- Verification status, Product and Batch not overwriting.

National systems (for the affected national system please consult the EVI):

- Partially limited availability due to high workload in Database.
- In the past, some GTINs were accidentally mixed together as one single product in the NMVS. The reason is that MAHs used misleading information in the NHRN field like "n.a.". The issue is fixed, however there is a backlog of these grouped GTINs which needs to be cleansed. Due to this mix-up the OBPs might receive duplicated serial number errors.
- The NMVS considers a pack to expire at the start of the expiry day instead of at the end of this day. So currently packs expire 24h too early.



EMVO's further actions

In order to ensure that OBPs receive the most accurate and up-to-date information on the issues affecting the EMVS, we have established a task force with our senior management and technical experts. This task force has temporarily relocated to a shared office room in order to facilitate the management of the current issues. We have a 2 hourly call cycle with the relevant IT suppliers, who are assisting us in this task. We are constantly monitoring the situation and will always provide OBPs with a full and frank assessment of Known Issues.

EMVO cannot impress upon you enough how seriously we are taking the current situation, and that we are working around the clock to resolve the current issues and ensure that OBPs can fully interact with the EU Hub. We will not rest until all outstanding issues in the EMVS are resolved.

EMVO will be using the [EVI \(European Medicines Verification System Information\)](#) tool on the EMVO website to communicate all issues relating to the EU Hub.

At present we have just over 650 subscribers to this system, which is a number far below those who would need to receive information published there. EMVO has publicised the release of this system and has communicated that we will be sharing the most up-to-date information via the EVI.

We strongly encourage all OBPs to subscribe to the EVI as the best means to receive immediate updates on all Known Issues in the EMVS.

In the event of any question or uncertainty, please do not hesitate to contact our Helpdesk:

Tel. Helpdesk: +372 611 90 44

E-Mail: helpdesk@emvo-medicines.eu

EMVO Team

European Medicines Verification Organisation

www.emvo-medicines.eu

helpdesk@emvo-medicines.eu

EMVO_LoA_0054