

LETTER OF ANNOUNCEMENT Preliminary root cause analysis (incident reference: INC-59107)

24th April 2020

Dear all.

Regarding the recent EU Hub outage, we plan to keep you informed regularly as we progress with the root cause analysis process. With this in mind, we have prepared this first report.

Chain of events:

16/04/2020 evening

The objective of the activity was to upgrade the Microsoft Azure Service Fabric within the EU Hub infrastructure. This upgrade had been successfully performed and validated previously in both the Integrated Test Environment (ITE) and Integrated Quality Environment (IQE). The upgrade is a fully automated process, orchestrated by the Azure platform.

The resulting changes brought by the Microsoft Azure Service Fabric upgrade were required as prerequisites to the EU-Hub Release 1.7, which was scheduled for Saturday evening (18/4/2020). The upgrade procedure was executed but was not completed successfully.

17/04/2020 all day

The result left the underlying infrastructure layer in a degraded state. However, some transactions were still being successfully executed. The fact that transactions that were still being processed, coupled with the desire to not lose any in-flight data, drove Solidsoft Reply's strategy of trying to repair the existing degraded system with the help of Microsoft.

18/04/2020

Solidsoft Reply continued to work directly with Microsoft to improve the service availability by repairing the underlying Service Fabric. Ultimately the option had been taken to completely re-install the system (service fabric and application). This was considered by all to be the only viable strategy. As the system was being completely re-built from scratch the Service Fabric upgrade and the Release 1.7 could be performed as previously planned. To mitigate any further issues when the data traffic from NMVS and OBP systems alike started up, the system capacity was significantly increased to meet the extra load. The system was up and running by 18:00 CET and data was flowing through the EU Hub from all parties.

We are now working towards identifying the root cause. It is likely that the investigation and review will take several weeks to conclude as we are highly dependent on the analysis of Microsoft. We will share an update of the root cause analysis as soon as there is a new status available.





First lessons learned and next steps

We have received a lot of feedback from different parties regarding our communication during the outage. We did our utmost during the incident to keep everyone informed. The hourly updates to NMVO and EMVO stakeholders were very well received. However, we noticed that the communication towards the OBPs must improve. Therefore, we have decided to enhance our communications through a solid communication process. Additionally, we will ensure that OBPs receive more frequent and detailed information regarding incidents in a timelier manner.

We will also work together with our supplier to accelerate failover processes in case outages occur and, of course, will put additional preventive actions in place. The further investigation will also include a full understanding as to why the specified disaster scenario fail over systems did not appear to be available.

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

Tel. Helpdesk: +32 (0)2 657 00 08

E-Mail: helpdesk@emvo-medicines.eu

EMVO Team

European Medicines Verification Organisation

www.emvo-medicines.eu
helpdesk@emvo-medicines.eu

EMVO © 2020. All rights reserved.

