EUROPEAN MEDICINES VERIFICATION ORGANISATION

EMVO NEWSLETTER

Friday, May 24th 2019

WHAT'S NEW AT EMVO:

NMVO update

Last week, Kristina Von Sydow provided the first NMVO contribution to this newsletter and gave an overview of FMD implementation in Sweden.
This week, Ricardo Valente, the General Manager of MVO Portugal, gives an insight to the situation in Portugal.

Transition period and alert monitoring

As defined in Informative note 020CD100.20.200 published by INFARMED, I.P. on January 28, 2019, until further notice, there is a transition period during which the Delegated Regulation is fully in force, except with regard to procedures in the event of an alert (the operation must continue and the medicine be supplied, unless the anti-tampering device has been damaged).
Following what is defined in the referred note and in order to eliminate alerts related to system technical issues, MVO Portugal has monitored on a daily basis the alerts generated by the system and collaborated with MAHs, end users, scanner suppliers, software suppliers, EMVO and other NMVOs to solve the identified problems. It is essential that all those involved take the necessary actions so that the elimination of false alerts is achieved as quickly as possible.
Taking into account the information known to date and without prejudice of further instructions that may be issued by INFARMED, I.P., it is expected that the full stabilisation of the verification system will be achieved from the end of 2019 onwards.
To date, the alerts generated so far have in most cases had one of the following causes (arbitrary order):

- Incorrect reading or interpretation of data by scanners
- Data on products, batches or packs not loaded into the system or loaded incorrectly
- Technical problems in the end-user software

First three months after go live

In the first 3 months after the entry into force of the Delegated Regulation, the stabilisation of the verification system has been occurring as expected. There has been a significant increase, week after week, both in the number of packs loaded into the national repository and in the number of transactions carried out (verify, decommissioning, etc.). Currently more than 75 million packs are registered in the repository and the average number of transactions per week is around 320,000. On the other hand, the volume of alerts has been falling steadily.

It is imperative that all entities (Wholesalers, Pharmacies and Hospitals) successfully complete the onboarding process, under risk of non-compliance with the provisions of the Delegated Regulation. Currently, 69 wholesalers (that handle approximately 99% of the packs), 2.788 pharmacies (95% of the total number) and 26 hospitals (of 111) are connected to the national repository.

Whenever a pack bears a unique identifier (even if there is also a code 39), operations must be carried out on the basis of this identifier by reading its 2D code, and must proceed to verify and/or deactivate the pack in accordance with the rules defined in the Delegated Regulation.

For more information, please visit our website on **https://mvoportugal.pt/en/!**

EMVO's support for OBPs

One key element of EMVO's mandate from its stakeholders was to provide a means for pharmaceutical companies to connect with the European Medicines Verification System (EMVS), and therefore to be compliant with the Falsified Medicines Directive 2011/62/EU (FMD) and the Commission Delegated Regulation (EU) 2016/161.

To achieve this and ensure the security and efficiency of the system, the concept of On-boarding Partner (OBP) has been created. On-boarding one corporation through a single OBP also aims to ease the process and help companies through the process of connecting to the EMVS.

However, in addition to this support when connecting to the system, we are also providing a comprehensive system of support for OBPs when they have already connected.

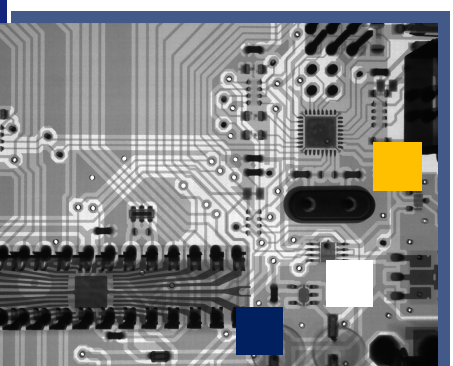
When a ticket is logged, by submitting a query to our Helpdesk email address (helpdesk@emvo-medicines.eu), it is then immediately assessed by our Level 1 support colleagues.

This level of support is provided to OBPs on the most routine issues, with roughly 60% of the tickets we received being resolved at this level.

If an issue is seen to be more difficult to resolve, it is immediately escalated to the 2nd level of support and passed to an EMVO colleague specialised in the specific topic of the ticket. It is then possible that an enquiry is escalated to the 3rd level of support, which involves the direct involvement of senior management staff at EMVO and the Hub IT provider. This is to ensure that the most difficult and pressing enquiries are handled properly.

It is, of course, our aim to provide a swift resolution to all enquiries and we hold regular review sessions to ensure that all requests made by OBPs are answered as quickly as possible.

By providing this triaging of requests, and a multi-level support structure, EMVO is committed to ensuring that OBPs are able to interact fully with the EMVS. We see this support function as being crucial to our ongoing work, and we want to assure OBPs that we will continue to improve our support.



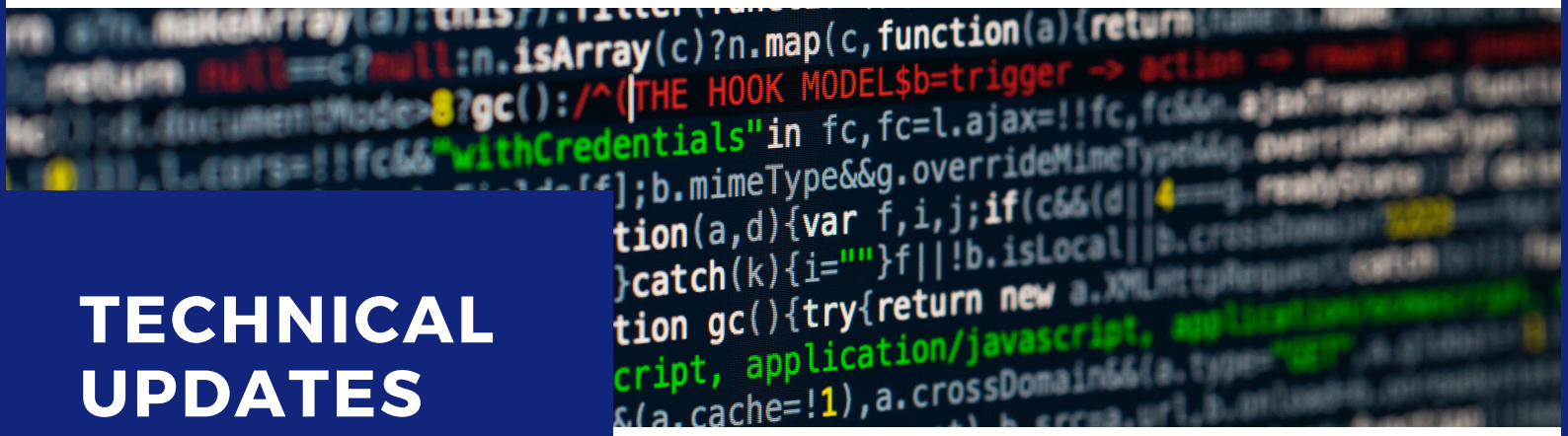
Making the best use of EMVO's Helpdesk

We want to be able to provide the best possible assistance for OBPs, and swiftly resolve any outstanding issues they may experience.

We ask that when OBPs experience an issue with the EMVS, they raise a ticket with EMVO's Helpdesk, and create only one ticket per issue.
When and OBP creates a ticket, they will be issued with a reference number related to their case. We ask that OBPs state this reference number when sending further emails related to the same case. This allows us to fully track all communications on the same topic.

This not only allows us to provide the dedicated support listed above, but also to identify and spot trends as they develop and to structure our operational resources accordingly. In addition to this, if you contact our Helpdesk by phone we would ask that you have your CP Number (the unique identification code corresponding to your OBP company) and contact details to hand.

EMVO will notify OBPs by email as soon as our Helpdesk considers that we have provided the necessary information related to an outstanding issue. We will then set the status of your query to "resolved". At this point, the requester will have 3 business days to re-activate this ticket in case of further questions or uncertainty, before the ticket is set to "closed".



TECHNICAL UPDATES

Technical issue
On 20th May, EMVO announced in the EVI that one of the root causes for the failure of Inter-Market Transactions has been identified.

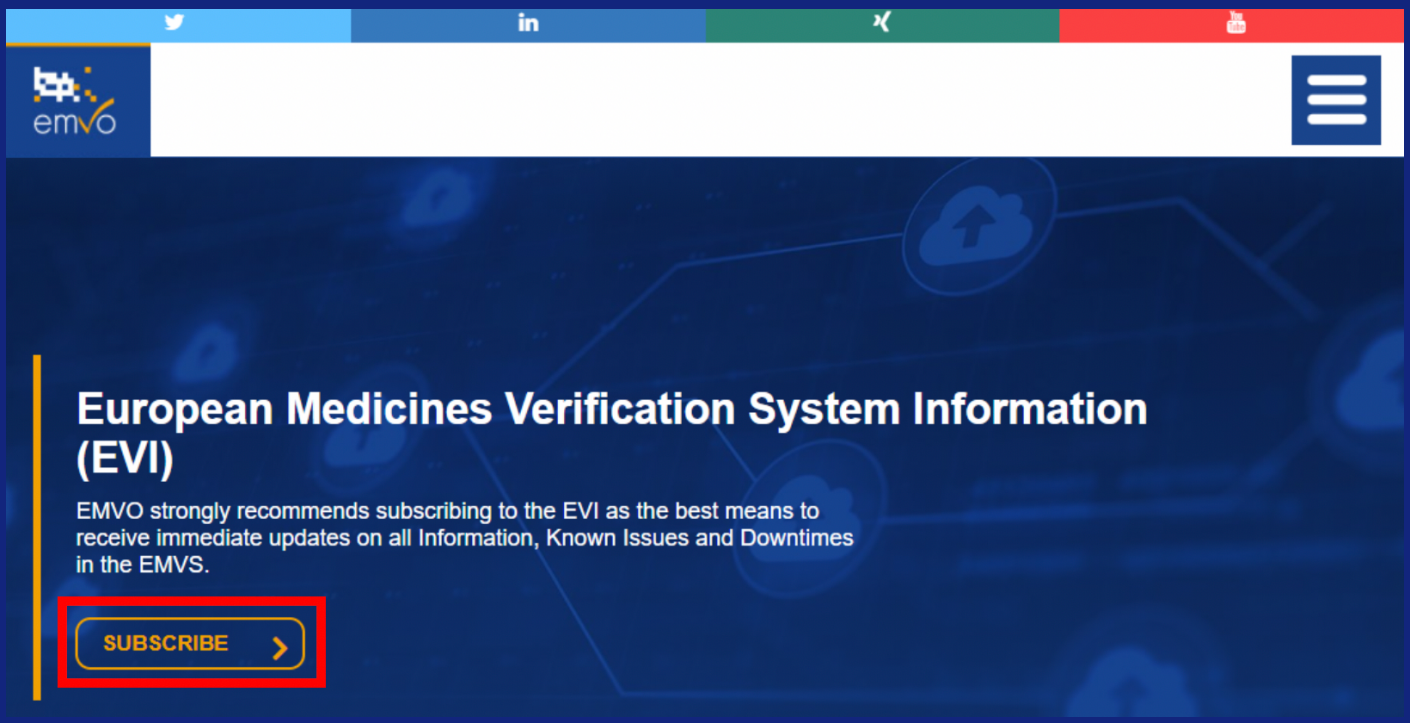
Root cause
All systems within the EMVS must use the same format for timestamps, which is currently not the case.

What next?
A standardised EMVS format will be brought forward to correct this problem. The EU Hub and the national systems will all implement this change. This issue has been raised to the relevant EMVO working group and we will provide further updates.

If you require any further information, please consult the full document here: https://bit.ly/2QgXo0n

European Medicines Verification System Information (EVI)

We strongly encourage all interested parties to subscribe to notifications from the EVI tool on our website (see next page). This is the best way to receive technical updates related to the systems of the EMVS, with general information also being posted here alongside Known Issues and Downtimes.



EMVO's Helpdesk

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