EMVO Newsletter 26 April 2019

Dear all,

Welcome to EMVO's first regular newsletter. In order to meet the needs of the Operational Phase of the EMVS, here at EMVO we believe that establishing and maintaining a regular form of communication to those interested in our work is necessary.

What is more, we have been constantly improving our processes in the period since the European Medicines Verification System ('EMVS') launch on 9th February 2019 and we, therefore, have much to report on.

EMVO is pleased to announce that:

From this April onwards, EMVO will be issuing a newsletter every two weeks informing you about our activities.

We will be covering amongst others:

1. Technical updates going from any outstanding issue to upcoming updates on technical functionalities. These will mirror the information we publish via the EVI on our website.

2. A general news update, where we will be announcing developments in our organisation which are of interest to anyone with a stake in our work.

We believe that this newsletter will allow you to have a full overview of EMVO's activities and their positive evolution over time and hope that this information will be useful to you and that you enjoy receiving this publication.

Yours sincerely,

European Medicines Verification Organisation

EMVO Team
European Medicines Verification Organisation

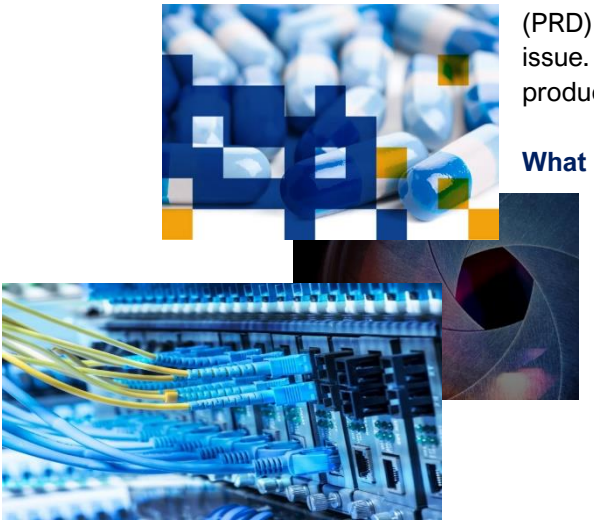
1. Technical updates

Technical issue

On 7th March, we originally communicated on a Known Issue and reported that Pack Disclosure Reports (PDR) were not currently being triggered by the EU Hub. As a consequence, OBPs did not receive pack disclosure reports as they should have.

Root cause

The root cause of this issue was identified and a fix was planned and rolled out to Production Environment (PRD) on Tuesday 23rd April. However, this initial fix has not yet fully resolved the issue. Pack Disclosure Reports can now be requested, but only for single market products.



What next?

EMVO will keep you fully informed on this topic. Please note that this issue does not prevent an OBP from uploading data to the Hub.

For further information, you can consult the full Letter of Announcement here: https://bit.ly/2UJINAf

Technical issue

On 8th April, following a problem of expiry date mismatch, EMVO contacted all OBPs in relation to expiry dates being uploaded to the EMVS which are different than those encoded in the Data Matrix Code on packs.

Indeed, it is a necessity that all OBPs ensure that the representation of the expiry date in the Data Matrix Code printed upon the pack is identical to that which is loaded to the EMVS via the EU Hub.

Root cause

In the first weeks of the Operational Phase, EMVO and the NMVOs witnessed that some OBPs encoded YYMM**00** in the Data Matrix Code and upload YYMM**31** (the last day of the month) in the EMVS. This was not correct and EMVO requested all OBPs to check if the expiry dates have been correctly uploaded as well as take corrective actions if it was not the case.

What next?

If your internal serialisation communication system cannot process DD="00" but your printing system can handle DD=00 resulting in you sending data to the EMVS that is not identical to that printed within the Data Matrix code, you should take immediate corrective action, for example by correcting the data via the help of EMVO Gateway.
For further information, you can consult the full letter of announcement here: https://bit.ly/2KzUSU3

Technical issue

On 25th April, we contacted OBPs to inform them that OBPs using the 2016 schema of the OBP interface must switch to the 2018 schema no later than September 30th, 2019 in order to be able to connect with the EU Hub.

Root cause

The 2016 schema of the OBP interface will no longer be supported as of 1st October 2019.

What next?

The OBPs which are not aware of whether using the 2016 schema of the OBP interface must consult directly with their IT provider/department.
For further information, you can consult the full letter of announcement here: https://bit.ly/2IGWyco

Technical issue

On 26th April, EMVO had officially announce a new release, *Release 1.5*, of the EU Hub.

Purpose

This new release of the EU Hub will include several functionality changes for the OBPs:

- Enhance the information that will be communicated via the Product Master Data Report;
- Simplification of the serial number randomization test;
- Enable bulk activity for sample packs;
- Make it mandatory, where applicable, for an OBP to provide a 'National Code' when distributing a pack to a country where this is a requirement (this is relevant to: Portugal, Austria, Germany and Spain);
- Release 1.5 will provide more distinctive descriptions of the '*O1 System Not Available*' messages

What next?

The planning for release 1.5 is that it will be rolled out in IQE by the end of May and that it will then be available in PRD by the end of June. EMVO will be releasing a dedicated Letter of Announcement on this subject, which will describe in detail the new release, its content and functionalities. This information will also be made available on the EVI: https://bit.ly/2WcyzFi

2. News

Alert Handling. On Tuesday 16th April, the EMVS Alert Management System workshop took place in Brussels. We brought together EMVO's stakeholders, NMVOs, and industry representatives, to discuss the development of an alert handling tool to meet the needs of the EMVS. This group will work during the coming months on a lasting, workable, and practical solution to the issue of false alerts.

We want to take this opportunity to assure you that EMVO is working on the issue of alert handling as its top priority. For instance, in recent weeks EMVO has authored guidance for End-User software providers, to ensure that the scanners and software of End-Users is configured in such a way as to ensure that false alerts are not generated. Furthermore, on 5th April EMVO contacted all OBPs to provide them with a list of alert specific contact information from the NMVOs. In providing this contact information, EMVO advised all OBPs to directly contact the relevant NMVO when they experience an alert which they suspect is related to End-User software or scanner misconfiguration. In addition to this, EMVO has also provided the NMVOs with the SPOC and SPOC Assistant details of the OBPs.

This means that an OBP and an NMVO will now be able to directly liaise and collaborate in the event that a pattern of alerts has developed in an NMVS with products related to that specific OBP.

For further information, you can read the full letter of announcement here: https://bit.ly/2FZQRT3.

We will continue to work in this regard by closely monitoring the alerts and their development as well as be proactive regarding the handling of false alerts.

EMVO's new Board of Directors took office in March at our Statutory General Assembly. After two years of dedicated service, Hugh Pullen (EFPIA) stood down as EMVO's President. At the meeting EMVO's General Manager, Andreas Walter, thanked Hugh for his contribution during his time in office and particularly for his work during the launch of the EMVS Operational Phase in February. In addition to this, Ilaria Passarani (PGEU) and Kasper Ernest (EAEPC) reached the end of their terms' as EMVO's Vice-President and Treasurer respectively.

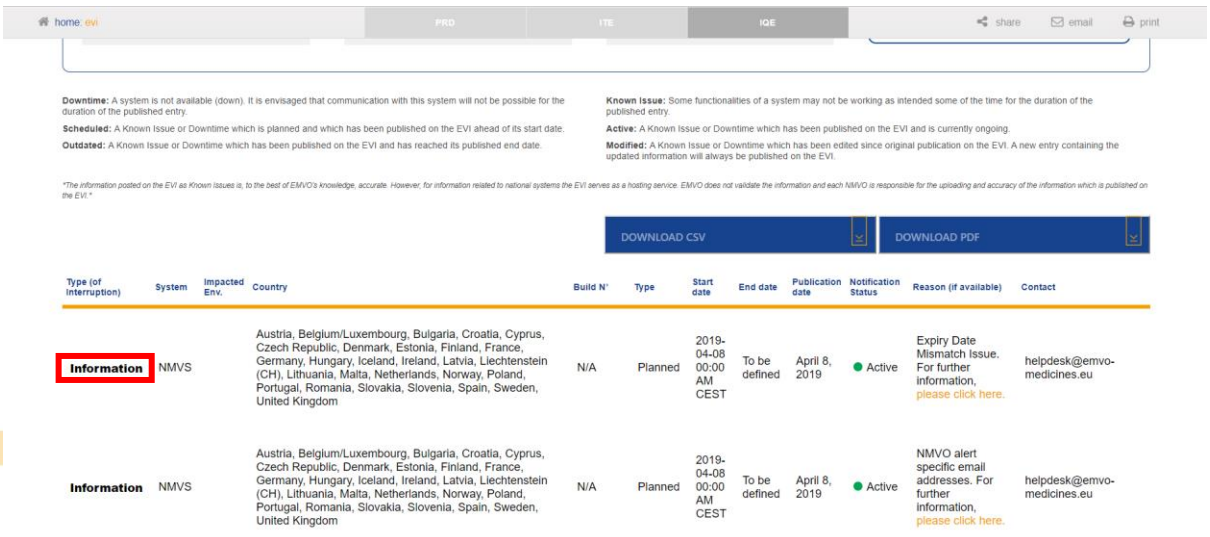
Adrian van den Hoven (Medicines for Europe) was subsequently appointed to serve as EMVO's President for a 2-year term. In addition, Monika Derecque-Pois (GIRP) and Nathalie Moll (EFPIA) have been appointed to serve as EMVO's Vice-President and Treasurer.

European Medicines Verification System Information (EVI). As we have stated in several of our previous communications, EMVO has developed the European Medicines Verification System Information (EVI) tool on our website in order to provide OBPs and all other interested parties with the latest information on the systems of the EMVS.

EMVO is responsible for the entries listed for the EU Hub, OBP Portal and the EMVO Gateway, with each NMVO being responsible for the entries listed for their NMVS.

Since we launched the EVI on our website, we have acted on feedback from the users of the tool and have added new functionalities to the EVI. We believe that the EVI is now tailored to the requirements of its users but can assure you that we will ensure that the EVI is dynamic to changing requirements. EMVO is pleased to inform you that a new function is now available on the EVI page: "Information". This category is listed alongside Known Issues and Downtimes, and is intended to allow the visibility for Letters of Announcement which relate to the issues listed on the EVI. We believe that including all relevant information on the EVI will be of benefit to subscribers, and this new functionality follows this principle.

We strongly encourage OBPs and all other interested parties to subscribe to the EVI. Notifications from the EVI are the best way to stay up to date with the latest developments in the EMVS.


home: evi PRD ITE IGE share email print

Downtime: A system is not available (down). It is envisaged that communication with this system will not be possible for the duration of the published entry.
Scheduled: A Known Issue or Downtime which is planned and which has been published on the EVI ahead of its start date.
Outdated: A Known Issue or Downtime which has been published on the EVI and has reached its published end date.
Known Issue: Some functionalities of a system may not be working as intended some of the time for the duration of the published entry.
Active: A Known Issue or Downtime which has been published on the EVI and is currently ongoing.
Modified: A Known Issue or Downtime which has been edited since original publication on the EVI. A new entry containing the updated information will always be published on the EVI.

"The information posted on the EVI as Known Issues is, to the best of EMVO's knowledge, accurate. However, for information related to national systems the EVI serves as a hosting service. EMVO does not validate the information and each NMVO is responsible for the uploading and accuracy of the information which is published on the EVI."

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Type (of interruption)	System	Impacted Env.	Country	Build N°	Type	Start date	End date	Publication date	Notification Status	Reason (if available)	Contact
Information	NMVS		Austria, Belgium/Luxembourg, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Latvia, Liechtenstein (CH), Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom	N/A	Planned	2019-04-08 00:00 AM CEST	To be defined	April 8, 2019	Active	Expiry Date Mismatch Issue. For further information, please click here.	helpdesk@emvo-medicines.eu
Information	NMVS		Austria, Belgium/Luxembourg, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Latvia, Liechtenstein (CH), Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom	N/A	Planned	2019-04-08 00:00 AM CEST	To be defined	April 8, 2019	Active	NMVO alert specific email addresses. For further information, please click here.	helpdesk@emvo-medicines.eu

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CLICK HERE TO GO DIRECTLY TO EVI

We also encourage OBPs to log tickets if they encounter an issue. One ticket corresponds to a single issue, there is no need to create news tickets regarding the same issue.

We advise our OBPs to send us separate e-mails per topic. This will help us to process and answer the requests more efficiently.

In the case you would contact our Helpdesk via phone, please have your ticket number, CP Number (the unique identification code corresponding to your OBP company, which can be made of either 3 or 4 digits, preceded by the letters "CP") and contact details at hand.
The EMVO Helpdesk will contact you either via e-mail or phone to provide the requested information and the answer to your request.

You will be notified per e-mail as soon as the EMVO Helpdesk considers that the information you have been provided with resolves your case/answer. Your ticket will be switched into "*resolved*" status. As soon as the ticket is set to the status "*resolved*", EMVO gives the requester the possibility to reply within 3 business days in case of further uncertainty, questions or comments with regard to the raised ticket. If there is no reply within these 3 business days, the ticket will be automatically set to the status "*closed*".

Finally, you will receive an e-mail as soon as your ticket is set to the status "*closed*" in which event a reply to that ticket will neither reopen the ticket nor open a new ticket.

In case you would like to open a new ticket or follow-up on this request after the 3 business days allocated for that purpose, please send the Helpdesk a new e-mail with a new subject.
This will open a new request which will be processed as soon as possible.

EMVO's Helpdesk:

Telephone number: +372 611 90 44

E-mail Address: helpdesk@emvo-medicines.eu

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