EMVS Community Newsletter April 2024

30/04/2024

Welcome to the EMVS Community Newsletter

Welcome to the April 2024 Edition of the EMVS Community Newsletter! This month, we're focusing on Data Quality, featuring insights from EMVO, the Dutch NMVO, Accord Healthcare, and end-user perspectives from the healthcare sector.

Insights from NMVO

Information that is uploaded by the OBP is important for investigative purposes. If an alert is raised on a product of the MAH and investigation is needed, the

NMVO and/or NCA contacts the MAH based on the information that is in the alert.

Unfortunately, if an MAH has uploaded incorrect or incomplete data, the information in the alert is also incorrect or empty.

For example (see below): an empty "MAH name" field, for which more than 140.000 packs are uploaded in one month. An alert on any of these packs will not be easily traceable to an actual MAH. NCAs and NMVOs need to look for other information in the alert, such as product name and batch ID to find out who to contact about this alert. And have to hope that that information is available and correct…

MAH Name	MAH Id	Total packs
-	XYZCORP001	140608

The extra difficulty is that, once data is uploaded, this data cannot be deleted or corrected. "Old" mistakes stay in the system. Therefore correct and complete data is very important. NMVOs see the solution in using one unique MAH ID - preferably SPOR ID - and automatic pre-filled MAH details and/or 4-eyes checks on all data before it is uploaded into the EU Hub. This minimises human errors in data uploads.

Written by Dorien Verbree from NMVO

Enhancing Data Quality: Challenges and Strategies for OBPs

When it comes to uploading and maintaining data within the EU Hub, OBPs face critical challenges that demand robust strategies for effective execution. Several fundamental aspects form part of the process, from having the right systems &

personnel, gathering reliable source data to ensuring successful uploads and maintaining data integrity throughout.

One of the key challenges OBPs encounter revolves around understanding versioning within the EU Hub and navigating interactions with connection providers' systems. Establishing a direct connection via the EMVO Gateway has emerged as a strategy offering flexibility, especially for retrospective updates on Product Master Data versions and updating batch header data.

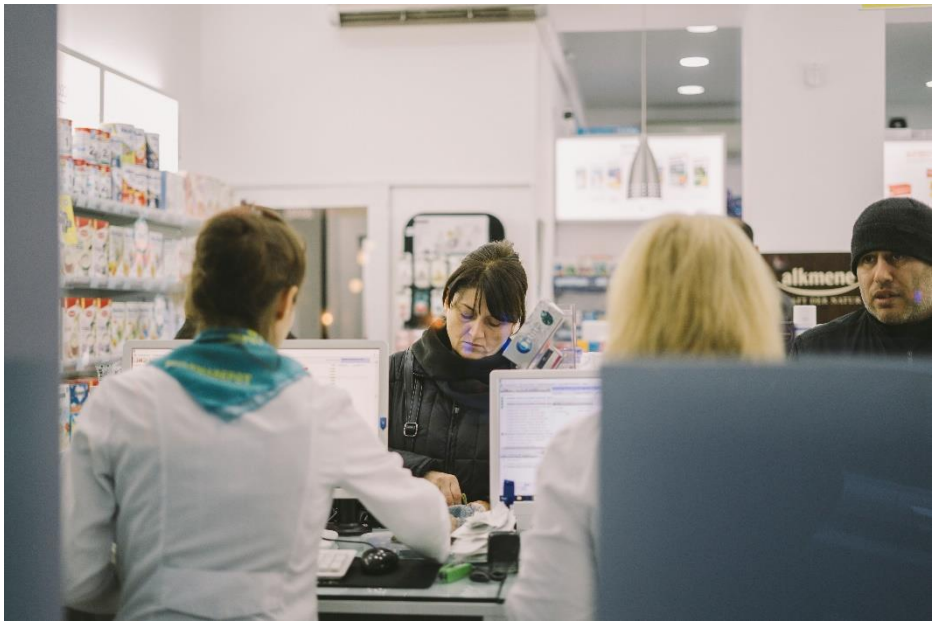
Formatting issues present another hurdle, with data handling nuances such as dropped leading zeros or hidden blank spaces posing risks to data accuracy. Additionally, differing data fields and system requirements across the CMO – MAH – EU Hub ecosystem necessitate systematic approaches to ensure end-to-end success.

Coordinating mass updates for Product Master Data demands careful planning. Segmenting and scheduling uploads during optimal system handling periods assists smoother processing, always checking for success.
Utilising connection providers' systems as a System of Record for Master Data ensures a single source of truth, while implementing data validation and mandatory fields in spreadsheets maintains integrity of the source data. Collaboration with external parties promotes shared goals and continuous improvement initiatives. Monitoring for EU Hub updates with SPOCs circulating information internally ensures teams can plan and are well informed of the latest news.

Furthermore, embracing best practices such as minimising manual data entry, making use of import/export functionalities and utilising test systems first will help strengthen data management processes.

In essence, enhancing data quality in the EU Hub demands a varied approach that combines robust strategies, collaboration with external stakeholders, and a commitment to continuous improvement. By addressing challenges proactively and implementing best practices, OBPs can navigate the intricacies of data management and will be well placed to help EMVO in their drive for data quality.

Written by Martin Hughes from Accord Healthcare



Product Master Data Quality and its impacts downstream. A pharmacy's view of data quality in the EMVS

The quality of product data in the EMVS can be improved. With millions of correctly performed transactions daily the quality issues are not related to the EMVS capability to verify and decommission unique identifiers ("pack data"). The need for quality improvements in the EMVS lie in the system's "Product Master Data",(PMD).

The PMD is used for identification of the product in the EMVS and contain the product code (GTIN), product name, batch, generic name, MAH name and MAH address among other information.

The issues that NMVOs and end-users often identify are incorrect naming of the product, multiple ways of spelling of the same MAH, data added into incorrect fields etc. Of course, most of the data is correct, but the amount of incorrect data is notable.

The PMD is used by NMVOs to provide information of the product, batch and MAH to the end-user and the data is also used in the NMVOs processes for alert handling and invoicing of MAHs. In the end-user software systems, the product name helps in the understanding of response messages from the NMVS. In the case of triggered alerts, the product name and MAH information gives context to the alert to the end-user, NMVO and MAH and can identify which product and pack generated the alert.

Is it such a big deal if the product name is incorrect or MAH name is spelled in different ways? An end-user can still decommission the pack even though

product information is incorrect, and a product can always be identified via the product code, right? Let's go back to the core purpose of the EMVS.

The core concept of the EMVS is to reassure that a pack in the legal supply chain is authentic. A simplified description of the fundamental functionality can easily be described and understood. Only MAHs can upload data in the EMVS and if a verified pack is found in the EMVS, the end-user can be sure that the pack is authentic.

Technically however, the functionality is much more difficult to understand, the system doesn't respond with a green or red light, there are hundreds of different response messages that can come back from the system. For a pharmacist, using the EMVS in the dispensing process and live in front of a patient, a clear and concise message is crucial for building and maintaining trust in the EMVS. For a pharmacist (and we assume for most coworkers in the medical supply chain) the name of the product is easiest and most straight forward identification method of a medicine.

The system must provide correct data to the end-user.

It is therefore a relevant question to ask if a system that doesn't even provide the correct name of the medicine really can tell if a pack is authentic or not? How can an Alert Management System be of any use or have high quality if the product name does not match with the pack that has generated the alert? How can the EMVS network reassure that the pack is from the correct MAH when the system does not know the name of MAH as stated in the SPC?

The quality of PMD must therefore be improved. For approved medicines, the product name and MAH information is always present in the SPC and the product master data in EMVS cannot be anything else than what is stated in the approved SPC.

Improvement of product master data can be maintained with changed functionality in EMVS-hub and aid to MAH. Cleaning up existing data is labour intensive but having correct data in EMVS is worth the effort. An EMVS with high quality and correct product data is essential for reassuring and maintaining end-user confidence in the EMVS. To create trust and commitment, high quality in the system is a cornerstone.

Written by Ludvig Möller and Helena Calles from e-VIS and Apotek Hjärtat

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EMVS Testimonial from Hospital AZ Sint Lucas

Discover the invaluable insights straight from the forefront of healthcare innovation in our latest article, where a prominent hospital shares their testimonial on the paramount significance of employing top-tier software and cutting-edge scanners. This testimonial holds particular relevance as the hospital, boasting an impressive 34,000 transactions in the National Medicines Verification System (NMVS) in March 2024, achieved an extraordinary alert rate of just 0.01%. Dive into their firsthand account to unravel the pivotal role of high-quality technology in ensuring seamless operations and enhancing patient care.

"When the EU FMD regulations came into effect, it brought an important burden upon our hospital pharmacy. Every afternoon, dedicated personnel had to manually scan all received boxes to comply with these new regulations. This process was perceived as extremely time-consuming, on top of the existing tasks such as unpacking goods, checking shipment notes, storing the goods, and validating the shipment notes in our pharmacy software. Even the inputting of expiry dates was done manually in our software.

This manual process proved to be highly error-prone, resulting in discrepancies between our software-based inventory and the actual stock. This led to complications in validating invoices and inaccurate backorder reports, often indicating unwarranted issues.

Fortunately, our hospital pharmacy software provider brought us relief in 2023 with the introduction of entirely new functionalities within their software. This advanced software solution integrates FMD scanning, validation of shipment notes, and inputting expiry dates into one seamless step. This implementation has resulted in significant improvements in our inventory management, smoother invoice validation, more accurate backorder reports, and has eliminated the need for separate FMD scans.

The importance of high-quality software and scanners cannot be emphasised enough, as they are vital in preventing errors in the input of product codes, serial numbers, lot numbers, and expiry dates. This directly contributes to preventing unwarranted alerts in the NMVS.
We still encounter monthly disruptions in our process due to suboptimal scans, resulting in 2 alerts in March 2024 in our hospital pharmacy.
But in March 2023 we had 69 alerts without the benefits of a better stock management.
Together with our software provider and our NMVO we will look for ways to reduce the number of alerts even further."

Written by Pharmacist Annelore De Zutter

Data Quality and the EMVS

Within EMVO, data quality is a topic of paramount importance that comes up daily in our conversations. High quality of data is fundamental in the EMVS not only to enable compliance with the regulation but also to ensure trust in data and its full usability. In addition, "incorrect data upload" was one of the most reported alert root causes across the NMVOs in 2022.

Crucial steps in achieving high data quality are:

1. Assessing the quality of the data in the system
2. Resolving the data quality issues
3. Monitoring the quality of the data in the system

In order to support data quality within the EMVS, EMVO has been focusing since the beginning of the year on the existing data fields in the PMD and PPD that will be made mandatory in the EU Hub (in order to comply with the DR) in January 2025.

1. After the first assessment, EMVO identified a number of OBPs with missing data in their PMD and PPD.
2. Afterwards, EMVO started a communication and education campaign to support the OBPs in identifying the missing data in their PMD and PPD.
3. In parallel, EMVO continuously monitors the progress of completion of the missing fields and will soon start monitoring the 'dummy data' (e.g., fields filled with '-').

To promote a coordinated and powerful approach to improve the quality of the data in the EMVS, EMVO participates (together with NMVO and EMVO Stakeholders representatives) in the EMVS Data Quality Working Group.

This group is currently working on an update of the EMVS Master Data Guide (to increase its clarity, offer more support to OBPs uploading data and improve data quality at the input source) and is exploring ways to tackle the issues around the duplicated MAH ID.

While we know that achieving high-quality data requires a lot of effort from OBPs, we strongly believe that the benefits will outweigh the burden of achieving it.

Written by Alice Borghi and Tracy Slosse from EMVO Data Quality Team

For any questions, please get in touch with our helpdesk: helpdesk@emvo-medicines.eu