

# Data Week



## Practical Cases

# Practical case: PMS Data Review



Let's take Asphaltion in a mock-up scenario as a laboratory with a **broad portfolio of medicinal products** in various therapeutic areas. To illustrate how the **IDMP implementation would work**, we will start with an initial review of the data. It is recommended to **prioritise the critical medicinal products** and the most relevant fields in **ESMP**. After this prioritization, the remaining non-critical products were analyzed.

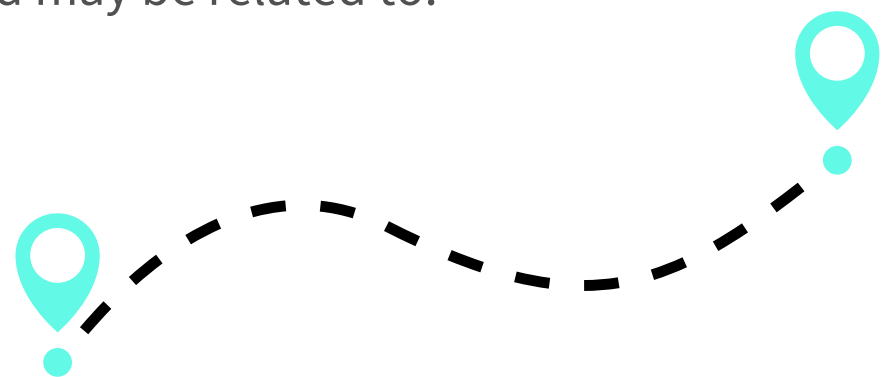
We present the following examples of errors related to the data migration to the PMS.

The root cause for any issues detected may be related to:

**A - xEVMPD**

**B - SIAMED**

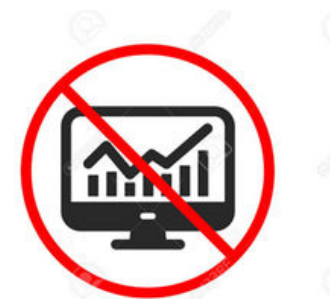
**C - Known migration issues**



## A - PMS Findings resulting from errors in xEVMPD

□	↓ PMS ID	Full Name	Authorised Dose Form	MA Holder	LOC ID	MA Nr.	Active substance	Authorisation Country	Authorisation Status	MRP / DCP / CP Nr.
	60000000000001	Asphatron 400 UI polvo y disolvente para solución inyectable y para perfusión	Powder and solvent for solution for injection/infusion	Asphalion S.L.	LOC-100019419	123456	ANTITHROMBIN III HUMAN	ES	Valid	
	60000000000002	Asphatron 400 UI polvo y disolvente para solución inyectable y para perfusión	Powder and solvent for solution for injection/infusion	Asphalion S.L.	LOC-100019419	123456	Antithrombin III	ES	Valid	

\*fictitious example



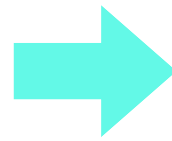
After the migration **from XEVMPD to PMS**, 2 PMS IDs have been generated. They appear to be identical, but upon review, we detected that the **substances were not aligned**.

# A - PMS Findings resulting from errors in xEVMPD

## How to proceed?

 EUROPEAN MEDICINES AGENCY  
SPOR - Substances Management System

### 1. Review of SMS List in SPOR



ANTITHROMBIN III HUMAN  
is SVG=0 and is duplicated  
as Duplicate of  
100000089108/SUB12917M  
IG



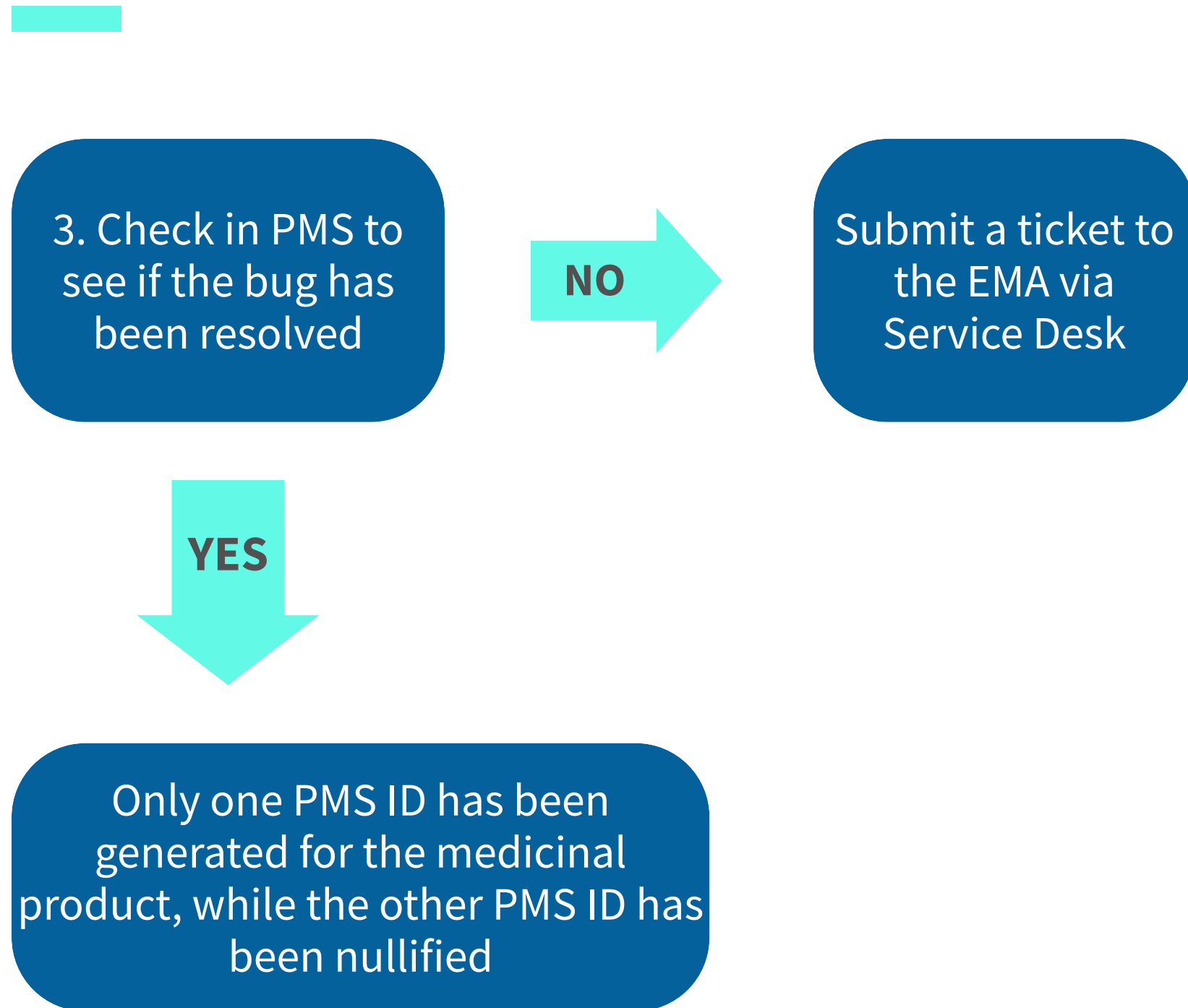
### EV Services

- ▶ EVWEB- ICSR
- ▶ EVWEB- Art 57 / XEVMPD
- ▶ XEVMPD Export
- ▶ XEVMPD Bulk update
- ▶ EV Data Warehouse
- ▶ EV Post

### 2. Align to Antithrombin III, SVG=1

Review in XEVMPD which presentations are not aligned with the correct substance, and update them with the correct term. Corrections in xEVMPD are required

## A - PMS Findings resulting from errors in xEVMPD



## B- PMS Findings caused by errors in SIAMED

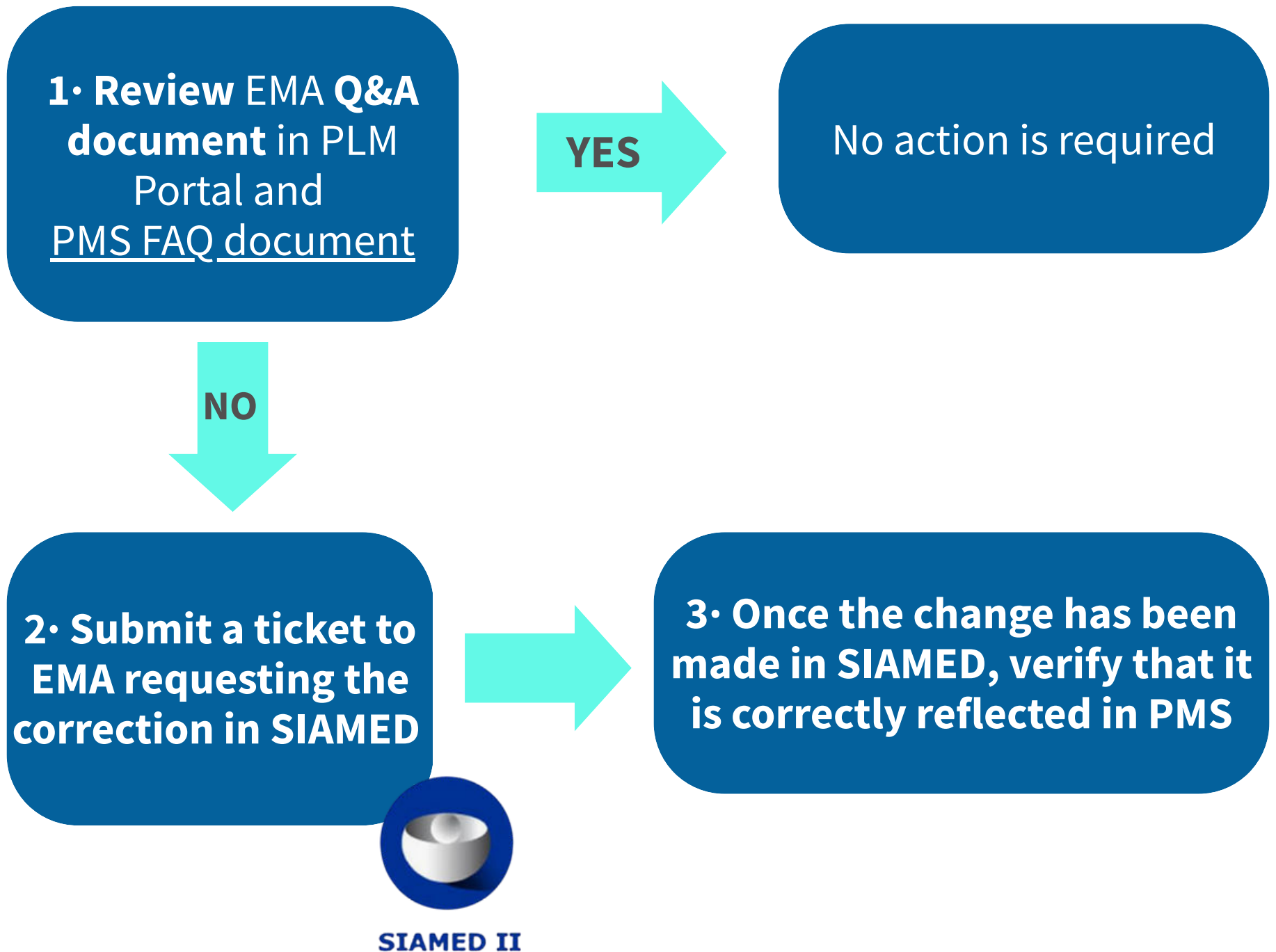
During the review of Asphalion's products in PMS, **an issue was again detected in the Manufacturing Business Operation in PMS-PUI** for one of the manufacturers of several medicinal products.

After reviewing the dossier information for the centralized medicinal product, we found that the **Business Operations do not match those reported in PUI-PMS**. Since the manufacturer's information for the centralized product is stored in **SIAMED**, this is suspected to be **the source of the error**.



## B - PMS Findings caused by errors in SIAMED

How to proceed?



## C - PMS Findings included among Known Issues listed by EMA

Review the **list of Known Issues** provided by the **EMA** and verify whether your identified bugs are included. It is also advisable to check for any information regarding the **expected resolution dates** of these issues.

This will help you **prioritize** and plan your actions accordingly. If you require further details on how to proceed or where to find this information, please do not hesitate to contact us.



# Contact us!

[info@asphalion.com](mailto:info@asphalion.com)

[www.asphalion.com](http://www.asphalion.com)



**25** years