EMA
EUROPEAN MEDICINES AGENCY

Managing product data quality in PMS: processes, known issues, status and best practices

21 July 2026

14:00 – 15:30 CEST

Presented by Marcos Fernández Gómez
PMS Product Owner

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Housekeeping – Q&A

- Many information will be provided on **specific DQ issues**.
- Please, **wait to see this information** before starting asking questions as those might be replied along the presentation.

Housekeeping – Q&A

Join at
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#ProductDQ

- Join via **QR code** or **slido.com** - *please provide your questions and comments in Slido only*
- **Send or upvote the questions you want to hear answered** – *before raising a question check whether its has been raised already and vote for it*

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.

- **Unanswered questions** can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and **the most relevant ones may be addressed** in other webinars or in the PMS FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.

Housekeeping – Webinar materials sharing

Presentation will be available at:

- EMA Event Web Page

Recordings will be available at:

- EMA YouTube Channel
- EMA Event Web Page

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Agenda

1. **Welcome**
   5 min
2. **Current state of Product Data Quality**
   25 min
3. ***PMS Customer Service***
   25 min
4. **Q&A**
   30 min
5. **Closing**
   5 min

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Aim of this webinar

Today's webinar provides an overview of the **current state of product data quality issues** identified through the **Product Management Service** (PMS). It also explains how to contact the European Medicines Agency (EMA) to **report findings and submit questions**.

DEEPEN YOUR KNOWLEDGE ABOUT PMS DATA QUALITY

Learn how to investigate product data quality issues, check their status and find the relevant guidance and resources.

UNDERSTAND HOW EMA ADDRESSES PMS DATA QUALITY

Learn how EMA investigates product data quality issues, identifies the appropriate resolution, and communicates the status and next steps to users.

COLLECT FEEDBACK & CLARIFY QUESTIONS

Address your questions to gain a clear understanding of product data quality status and how to report findings.

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DQ Issues

- EMA acknowledges that some products are impacted by specific issues.
- One of the biggest priorities for EMA is to resolve those issues so data can be reliable and usable by different consuming systems (e.g.: eAF, ESMP, IRIS, PSURs, etc)

- It is important to understand the extent of those DQ issues

Number of valid Medicinal Products

290,000

100%

Number of duplicated EV Codes **before** fix was implemented

25,000

8,6%

Number of duplicated EV Codes **after** the fix was implemented

600

0,2%

Number of duplicated products **before** fix was implemented

21,000

7,2%

Number of duplicated EV Codes **after the first round** of fixes was implemented

6,000

2%

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DQ Issues

- EMA acknowledges that some products are impacted by specific issues.
- One of the biggest priorities for EMA is to resolve those issues so data can be reliable and usable by different consuming systems (e.g.: eAF, ESMP, IRIS, PSURs, etc)

- It is important to understand the extent of those DQ issues

- Additionally, some of the issues reported by the applicants might not be issues or might be expected behaviors of the system. Users should be able to differentiate between a DQ issue or an expected result in PMS.

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DQ Issues

- MAHs should be familiar with the guidelines to understand when a product is impacted by a DQ issue.

↓PMS ID	Full name	Authorised dose form	MA holder	LOC ID	MA nr.	Active substance	Authorisation country	Authorisation status	MRP/DCP/CP nr.
600001860706	Umanbig 180 NE/ml oldatos injekció	Solution for injection	Kedrion S.p.A.	LOC-100001385	OGYI-T-21363/02	Human hepatitis B immunoglobulin	HU	Valid	IT/H/0166/001
600001654988	Umanbig 180 NE/ml oldatos injekció	Solution for injection	Kedrion S.p.A.	LOC-100001385	OGYI-T-21363/01	Human hepatitis B immunoglobulin	HU	Valid	IT/H/0166/001

Ingredients

Substance	↑Role
Human hepatitis B immunoglobulin	Active
Glycine	Excipient
Sodium chloride	Excipient
Water for injection	Excipient

Showing 1 to 4 of 4 entries

Ingredients

Substance	↑Role
Human hepatitis B immunoglobulin	Active
Glycine	Excipient
Sodium chloride	Excipient
Water for injection	Excipient

Showing 1 to 4 of 4 entries

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Examples are randomly taken and data might have been fixed by the time of the webinar.

DQ Issues

Ingredients

Substance	Role	Origin of the substance
Human hepatitis B immunoglobulin	Active	—

Substance code	100000089105
Substance type	Structurally Diverse - Plasma derived
Reference/Monograph standard	—
Presentation strength	**equal to** 540 international unit(s) **per** 3 millilitre(s)

Ingredients

Substance	Role	Origin of the substance
Human hepatitis B immunoglobulin	Active	—

Substance code	100000089105
Substance type	Structurally Diverse - Plasma derived
Reference/Monograph standard	—
Presentation strength	**equal to** 180 international unit(s) **per** 1 millilitre(s)

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Examples are randomly taken and data might have been fixed by the time of the webinar.

DQ Issues

Ingredients

Substance	Role	Origin of the substance
Human hepatitis B immunoglobulin	Active	–

Substance code	100000089105
Substance type	Structurally Diverse - Plasma derived
Reference/Monograph standard	–
Presentation strength	**equal to** 540 international unit(s) **per** 3 millilitre(s)

Ingredients

Substance	Role	Origin of the substance
Human hepatitis B immunoglobulin	Active	–

Substance code	100000089105
Substance type	Structurally Diverse - Plasma derived
Reference/Monograph standard	–
Presentation strength	**equal to** 180 international unit(s) **per** 1 millilitre(s)

- Ch. 7 and Ch. 9 explain that two EV Codes with different strength will be migrated to two different medicinal products.
- This is not an issue on PMS and XEVMPD should be updated. Once done, PMS will be updated and both packages will be migrated under the same medicinal product.

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Examples are randomly taken and data might have been fixed by the time of the webinar.

DQ Issues

- The PMS FAQ document provides information on specific topics so users understand how the data is migrated.

3.8. Will centrally authorised products with authorisation country NO, IS and LI disappear from the Product UI?

3.9. Why some medicinal products don't have an MA number?

3.10. The MedDRA version of XEVMPD and the Product UI don't match. Why?

- It is therefore important to review this document before users raise tickets as the answer might already be in this document.

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DQ Issues

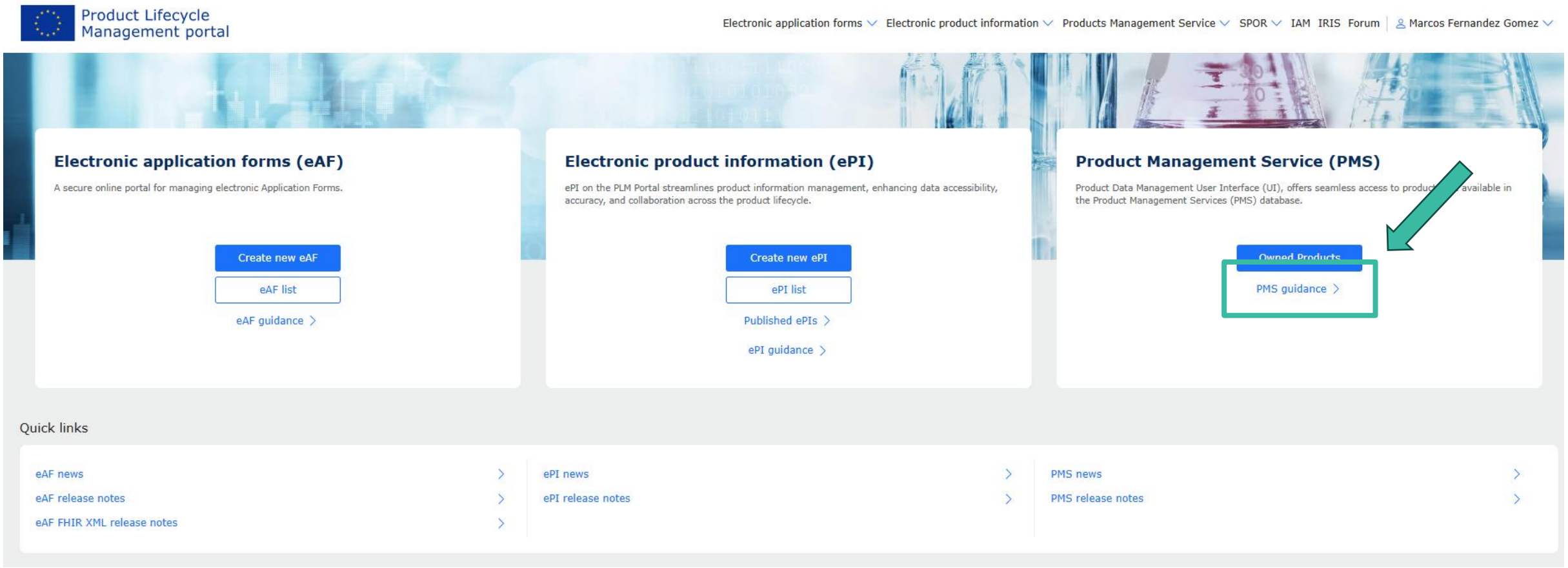
- The PMS FAQ document also provides a list of known issues, description, expected resolution time and action(s) for MAHs.

Issue	Description	Expected resolution date	Action for MAHs
Real duplicates merged in PMS – Procedure type	Please, review question 2.16 for additional information. In Q1 2026 it has been released a change that includes the Procedure type as a grouping element.	**Q1 2026**	For impacted products: Submit a dummy update on the EV Code whose procedure type differs from the one currently assigned to the medicinal product in PMS.
MA number at product level shouldn't be there	Products with multiple packages and different MA number per each pack size might have an MA number at product level, this shouldn't be the case based on the business rules from Chapter 2.	**Q4 2025**	Submit a dummy update to one of the EV Codes of the product to fix the issue.
Product updates from XEVMPD not processed	In some cases, when XEVPRMs contain a large number of EV Codes (inserts or updates), processing may be impacted. EMA is actively working on enhancements to further improve the handling of larger XEVPRMs.	Q2/Q3 2026	Try to send XEVPRMs with low amount of EV Codes when possible. Remember that the UTF-8 character set should be used.
Missing QPPV contact and Pharmacovigilance enquiry information data	QPPV code and the Pharmacovigilance enquiry information has been migrated to PMS but it is not shown in the Product UI	Unknown	None

DQ Issues

EMA will work with the PMS SMEs to improve the FAQ document and the way known issues are reported.

DQ Issues



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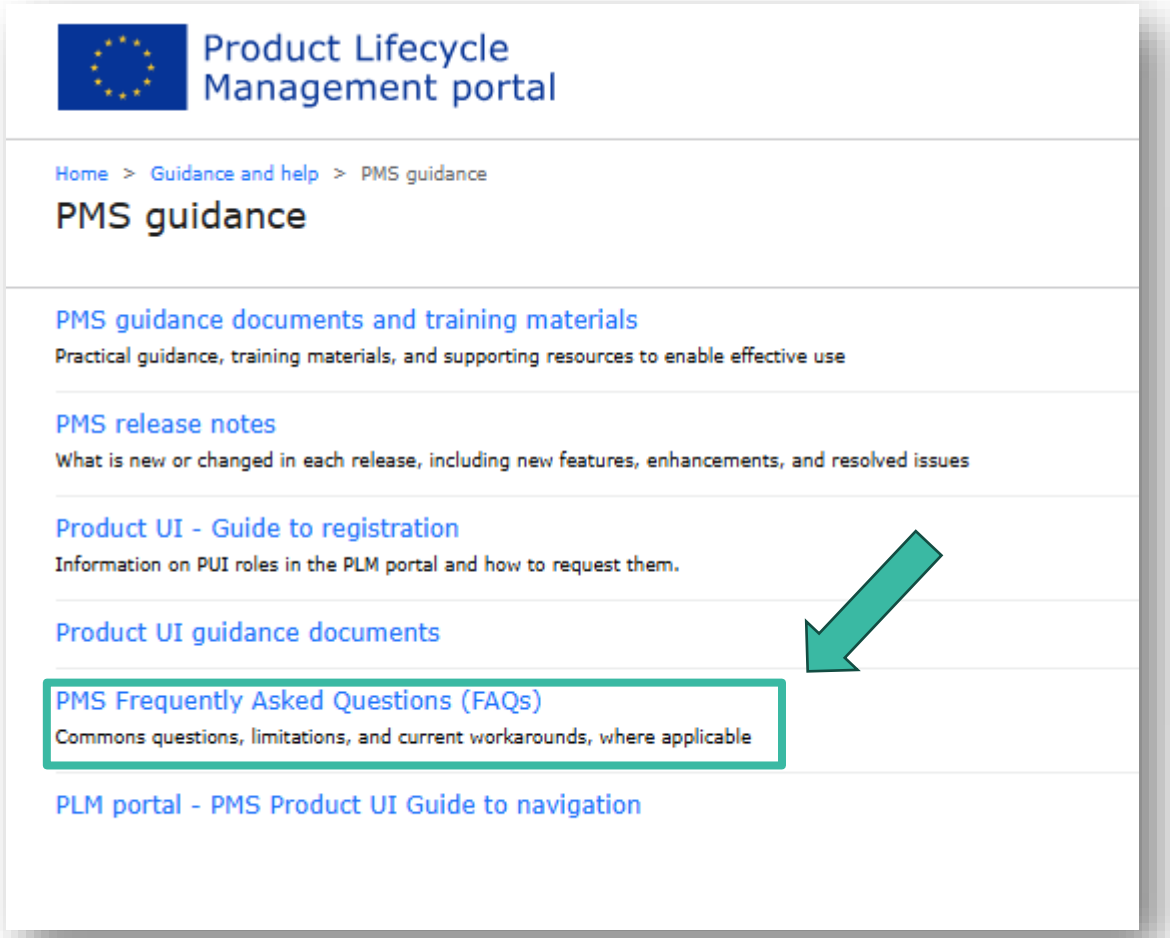
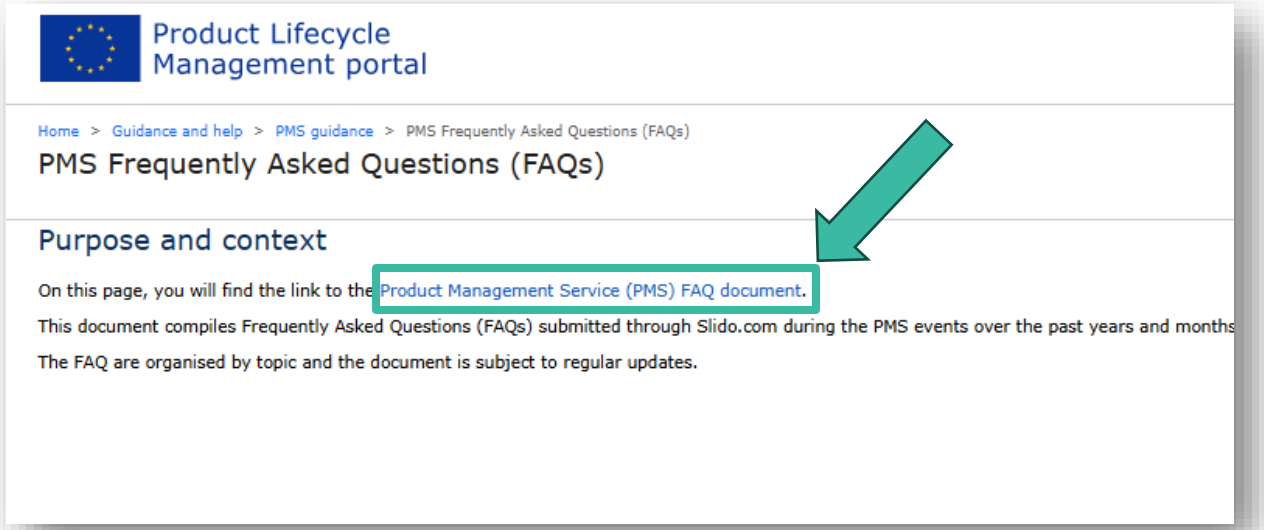
DQ Issues

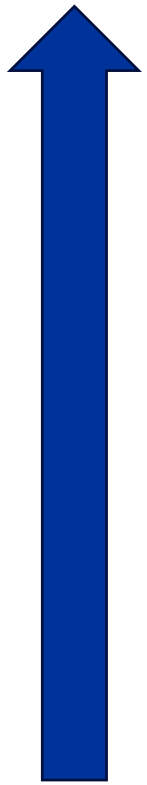




DQ Issues

- Not all issues have the same severity or impact.
- Some issues might have different impact depending the use case they support.
  - E.g.: issues on coded indications have no impact for the web-based eAF but will have an impact when PV activities consume data from PMS.
- EMA is therefore prioritising the resolution of these bugs based on the impact.

HIGH impact



LOW impact

- **Duplicated products**
- **Missing products**
- **MAH mapping missing**
- **Missing packages**
- **Duplicated packages**
- **Missing Units of Presentation**
- **Missing regulator's LOC ID**

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DQ Issues

Steps carried to resolve DQ issues in PMS

Identification of DQ issue affecting multiple products

Technical fixes of root causes driving data quality issues

Monitoring through Data Quality reports/dashboards.

Data fix of corrupted or inaccurate data to ensure reliability

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DQ Issues

Steps carried to resolve DQ issues in PMS

Identification of DQ issue affecting multiple products

Technical fixes of root causes driving data quality issues

Monitoring through Data Quality reports/dashboards.

Data fix of corrupted or inaccurate data to ensure reliability

- DQ issues affecting big number of products **will not be addressed individually** but as part of a coordinated data fix

  E.g.: duplicated products, wrong or missing regulators.

- **Notifications** are sent to PLM and PMS API registered users when a data fix is performed so products can be reviewed

- Remaining products affected by the issue will be address individually.

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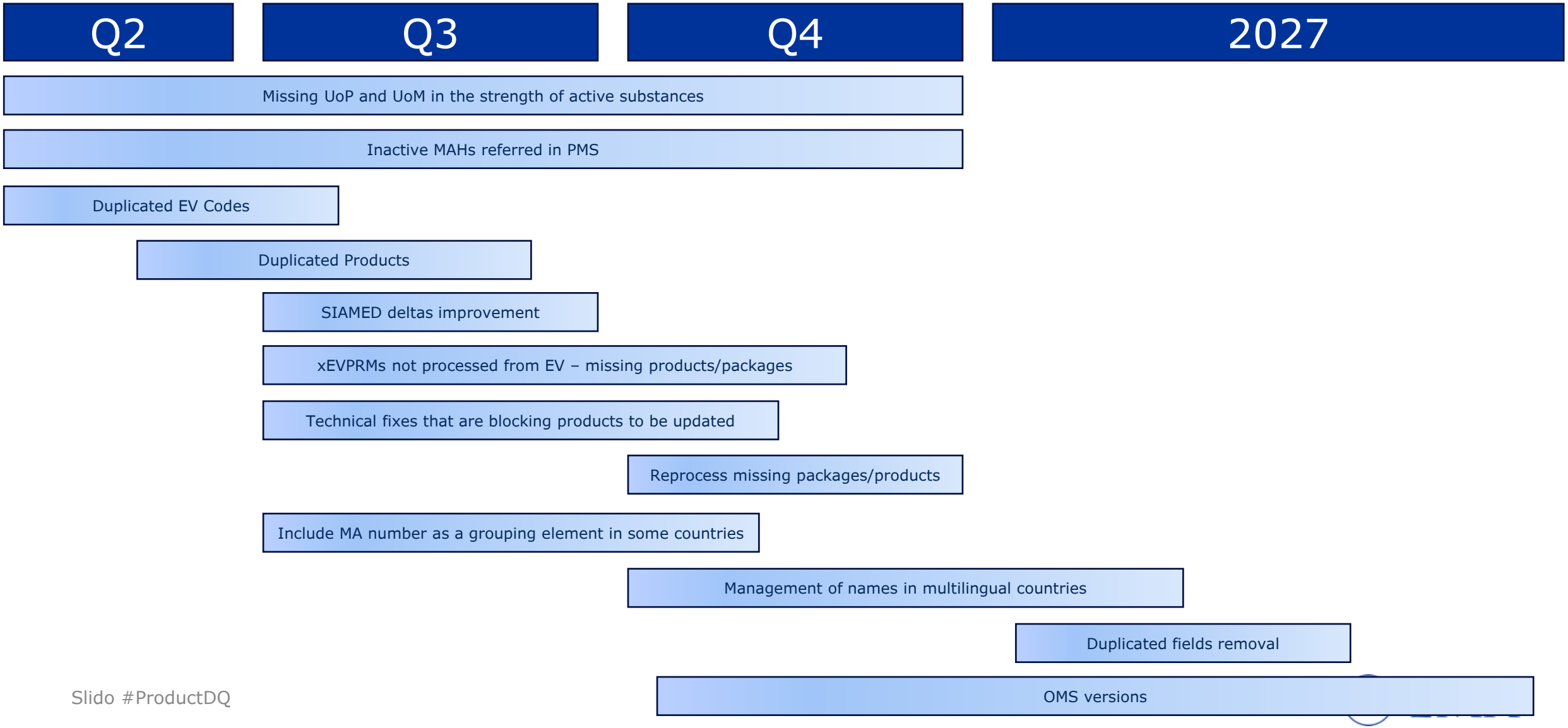
DQ Issues



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Q2	Q3	Q4	2027

Missing UoP and UoM in the strength of active substances

Inactive MAHs referred in PMS

Full name	Authorised dose form	MA holder
Propofol MCT/LCT/Fresenius 2% (20mg/ml), γαλάκτωμα για ένεση ή έγχυση	Emulsion for injection/infusion	[INACTIVE] Fresenius Kabi Hellas Single Member S.A.

Ingredients

Substance	Composition grouping description
Desogestrel	–
Substance code	100000083191
Substance type	Chemical
Reference/Monograph standard	–
Presentation strength	150 **per** 1 Tablet

```
<strength>
    <presentation>
        <numerator>
            <extension url="http://ema.europa.eu/fhir/extension/termVersion">
                <valueInteger value="1" />
            </extension>
            <value value="150" />
            <system value="http://spor.ema.europa.eu/v1/lists/100000110633" />
            <code value="UG" />
        </numerator>
```

Along the year, bulk fixes will be done to fix these two issues.

For inactive MAHs, updates can be submitted to XEVMPD by MAHs, but is preferable to perform a fix. Access is still granted to the products and eAFs can be created.

Action for MAHs: make sure the mapping between XEVMPD and OMS is done to the active location.

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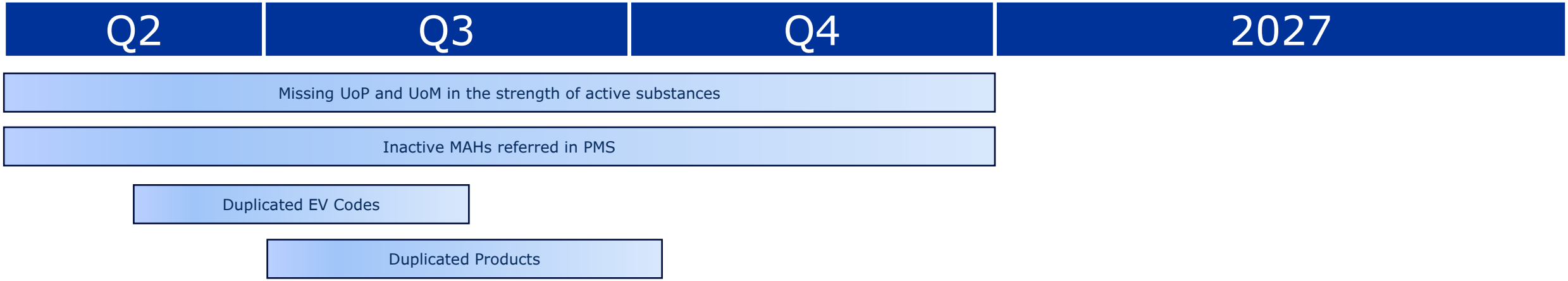
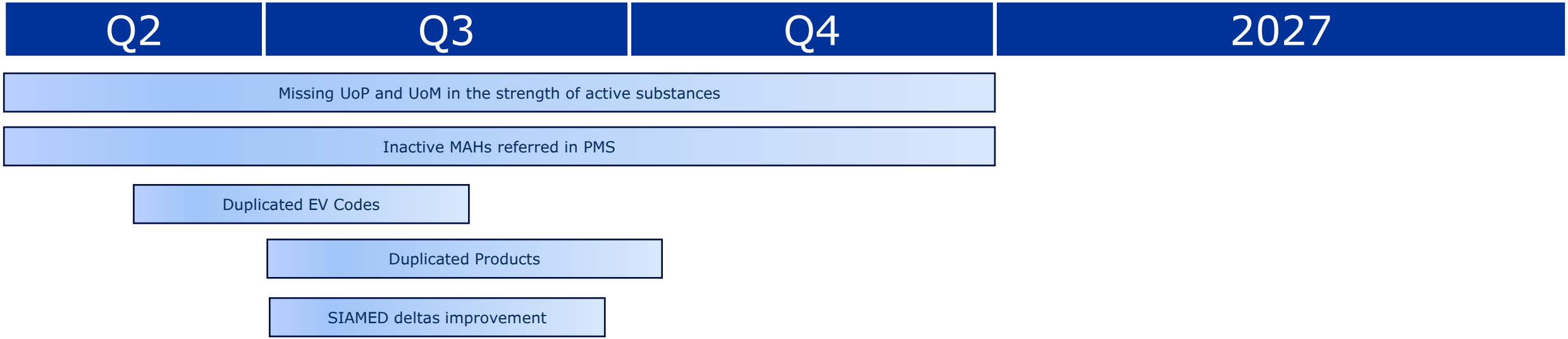


Removal of duplicated products and packages is one of the priorities for Q3.

Notification will be sent once the de-duplication is completed.

Action for MAHs: make sure it's a real duplication. Check active substances, strengths, etc. If needed, update the data in XEVMPD. Review Ch. 7 & 9 for additional information.

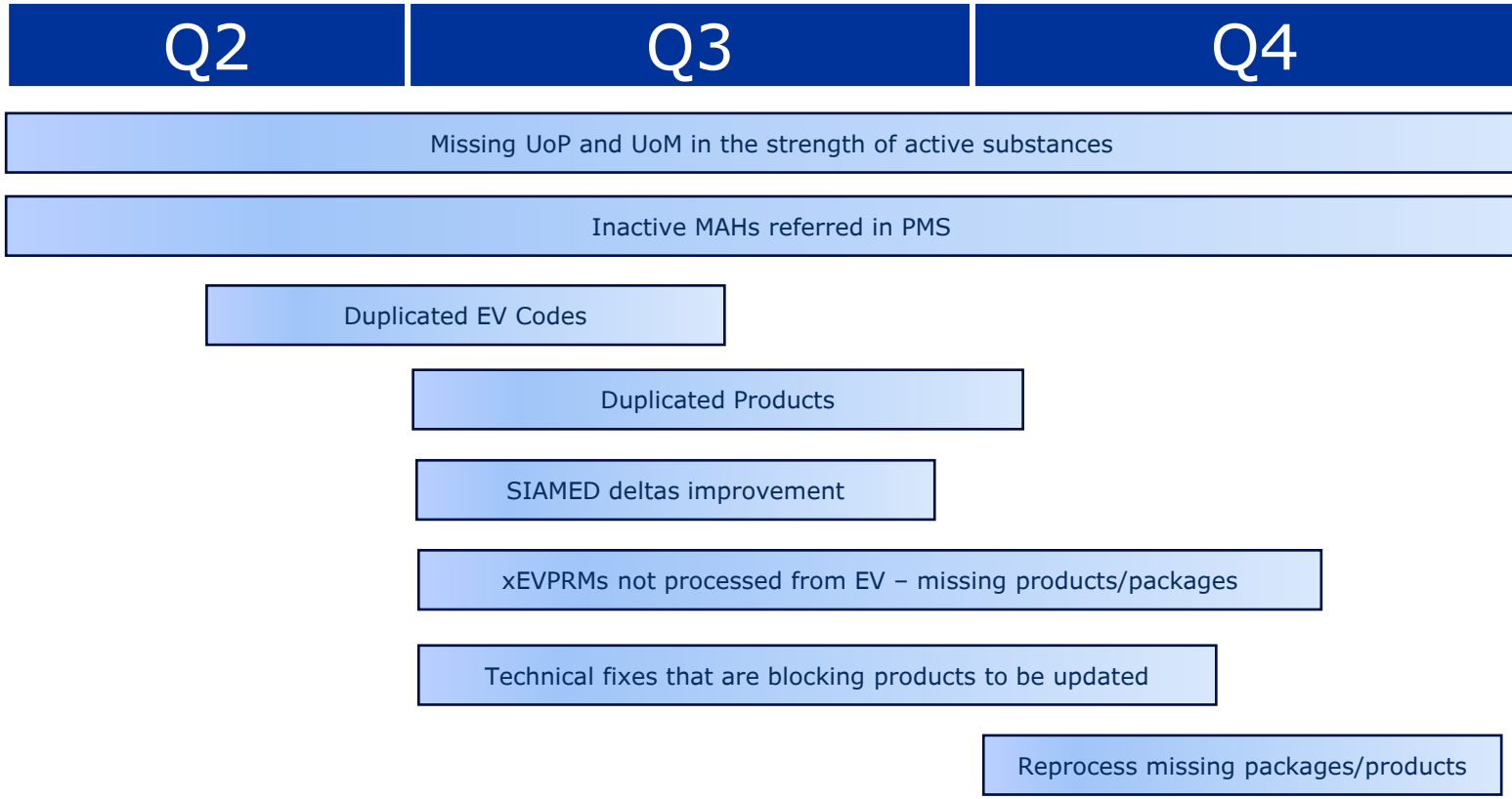


Current behavior:

- Missing updates
- Duplication of fields (RoA, pharmaceutical product, etc)

Those issues will be fixed with the improvement.

Action for MAHs: review CAP data and open tickets for missing information or discrepancies except for duplication of fields.
Make sure to read Ch 3 in case of MBOs: SIAMED captures high level terms for MBOs.



Current issue:

- Some XEVPRMs are not properly processed in PMS leading to missing packages/products.
- Some products are not updated due to a technical issue that has been identified.

Action for MAHs:

Send small XEVPRMs (less than 50 EV Codes within the same message, if possible, 10 EV Codes per EVPRM).

Don’t send an insert of an organization together with inserts or updates of EV codes (do it separately).

For missing packages, you can send individual dummy updates in XEVMPD. This will trigger the generation of the packages in PMS.

Open a ticket for missing products/packages.

Do not open tickets for missing updates unless affecting auth status or MAH change

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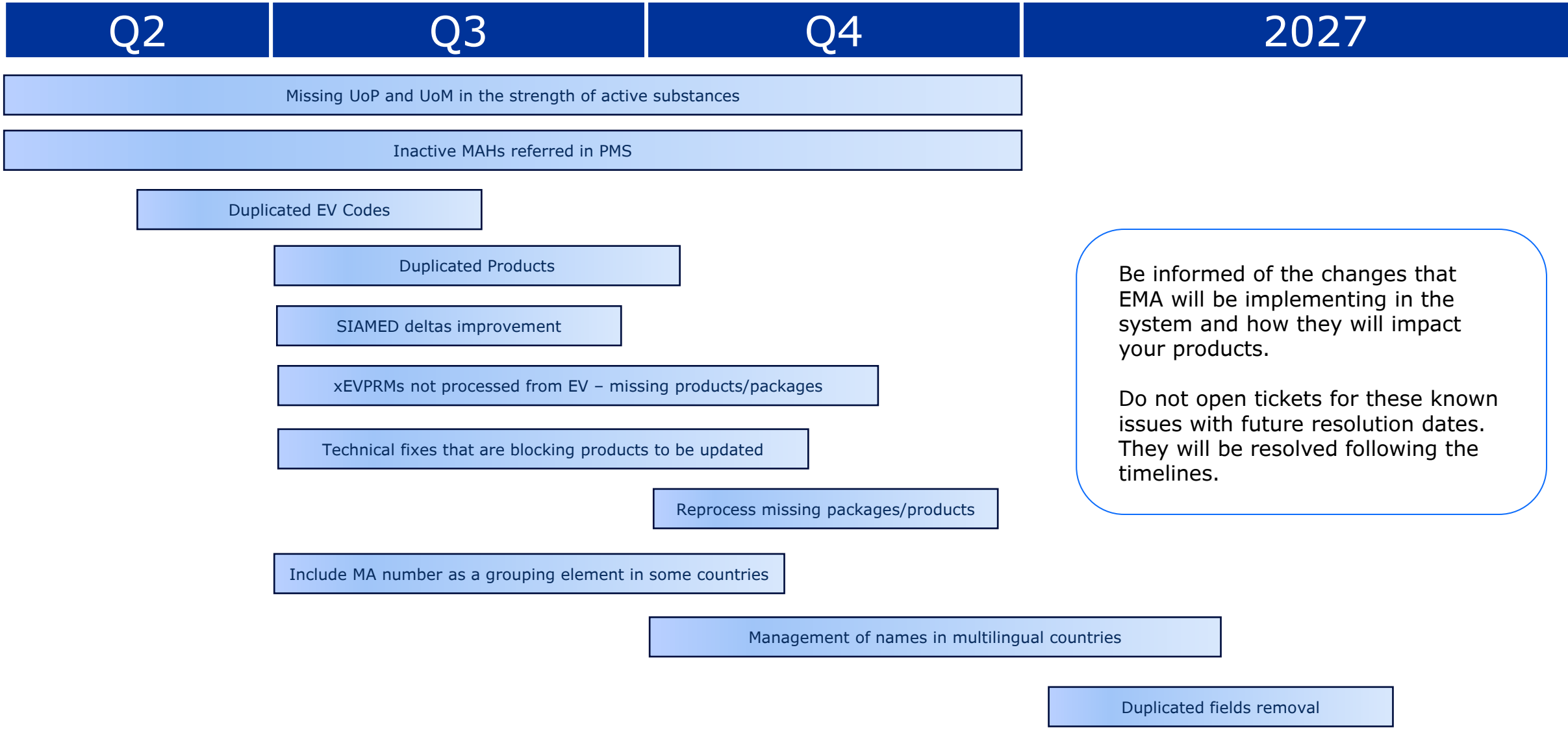
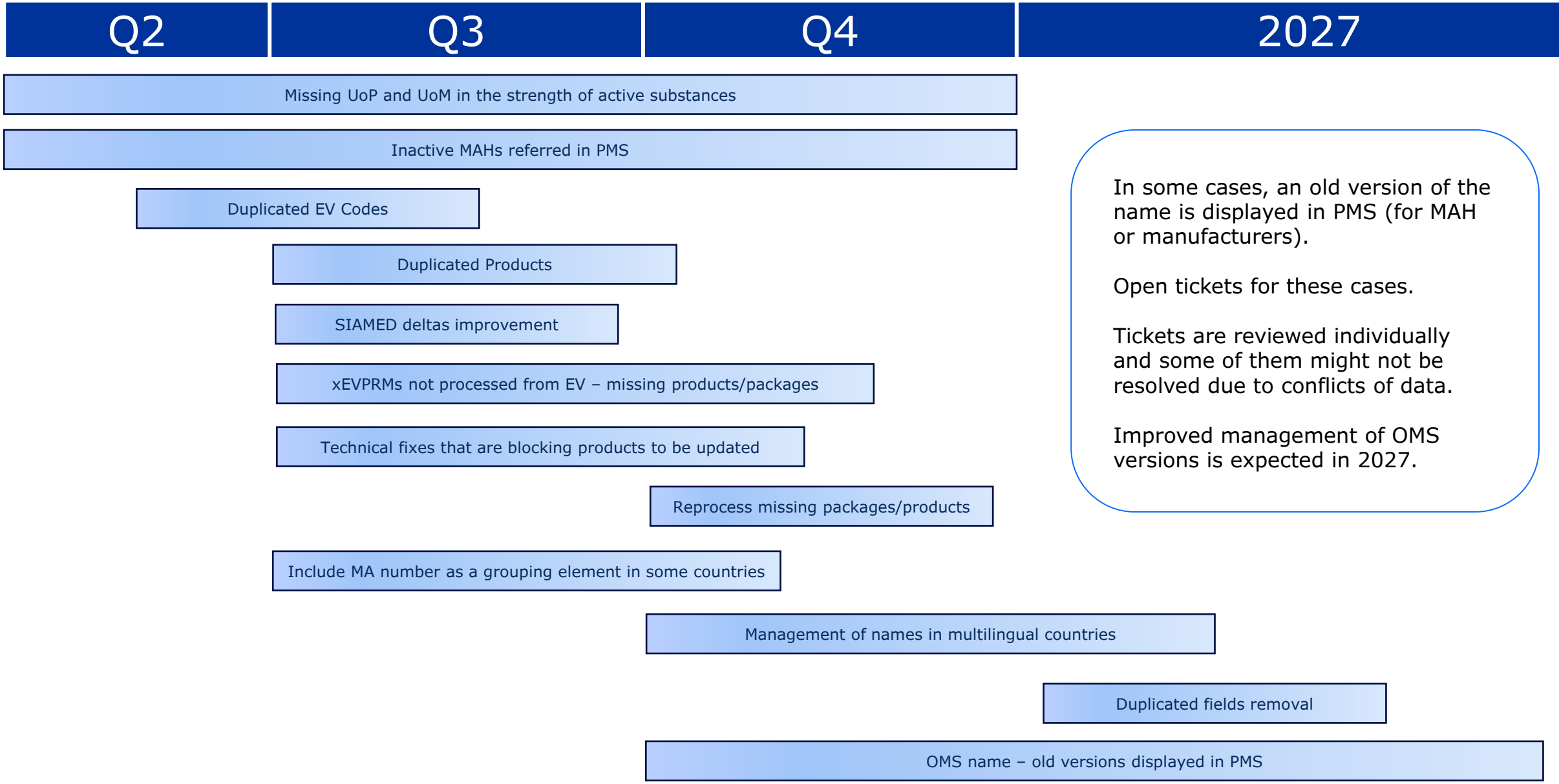


Be informed of the changes that EMA will be implementing in the system and how they will impact your products.

Do not open tickets for these known issues with future resolution dates. They will be resolved following the timelines.



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DQ Issues - summary

Do not open tickets for:

- Known issues with an expected resolution date
  - Duplicated products
  - Missing UoP
  - etc
- Updates not propagated to PMS from XEVMPD when not affecting critical values such as:
  - MAH
  - Authorisation status
  - ATC Code
- Missing packages (if they are not for critical products) – try to send individual updates so the system picks them

Open tickets for:

- Issues related to CAPs (except duplicated fields)
- Missing products or critical packages
- Issues resolved but still impacting your product

- Check EU IG and FAQ before opening a ticket.
- Raise one ticket per product unless the same issue is impacting many products (big tickets with many information makes it very difficult to handle).

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DQ Issues - summary

EMA is committed to resolve all issues.

Priorities are taken based on use cases where PMS data is supporting and criticality of the issue.

First use cases are shortages – ULCM & web-based eAF

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PMS Customer service

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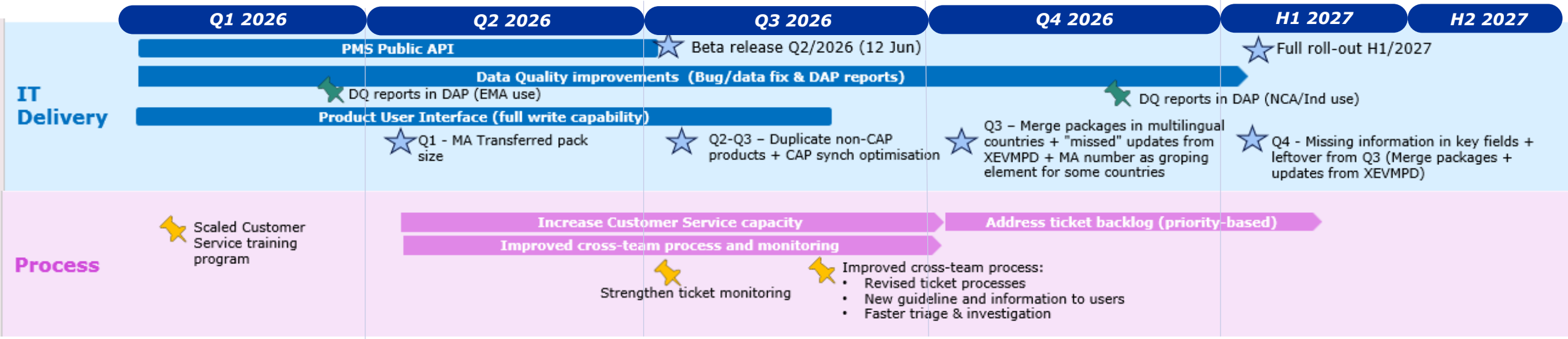
2026 PMS Customer service improvement roadmap



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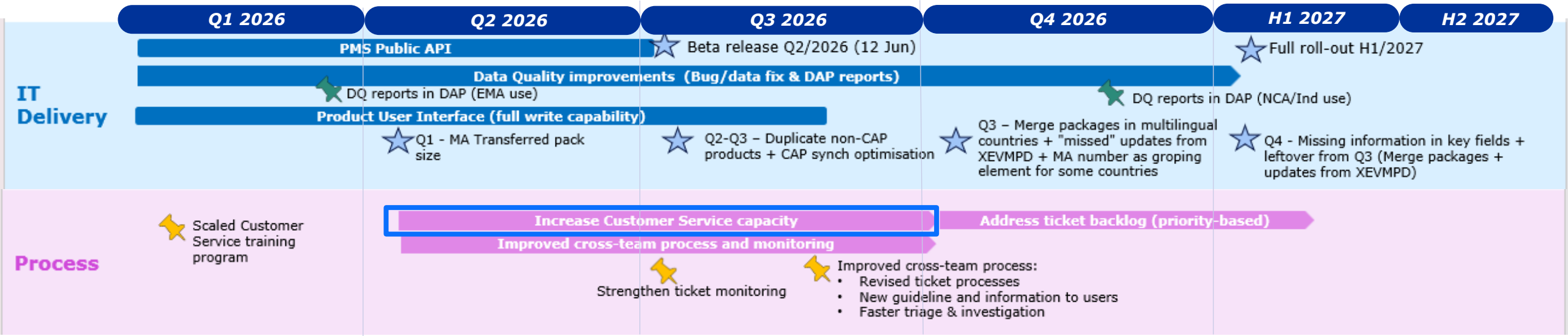
2026 PMS Customer service improvement roadmap



Meeting growing demand and committed to better customer services by:

Increased Customer service capacity

- **Recruit, train and onboard**
- **Structured onboarding programme** (May–October 2026), including training, mentoring and continuous knowledge updates.

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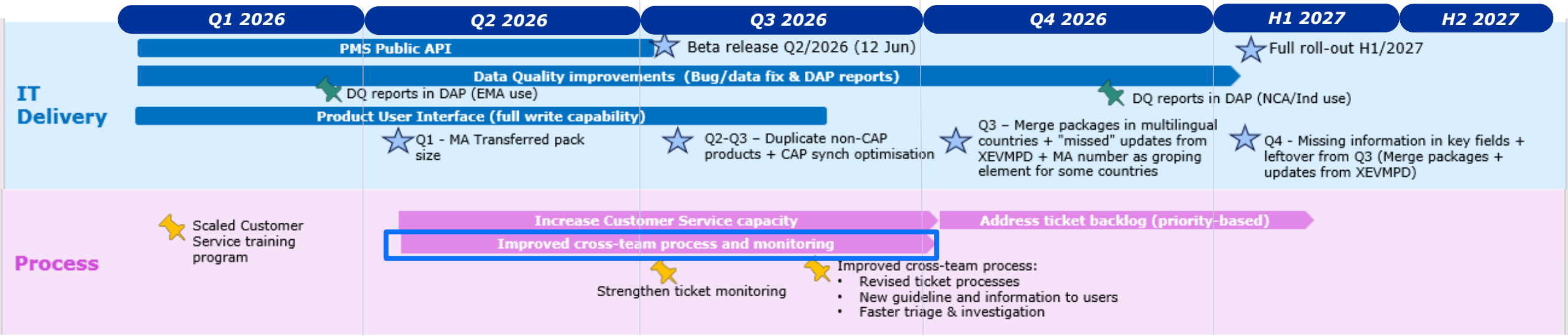

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- Faster triage & aligned ticket prioritisation
- Faster allocation and resolution
- Increased monitoring
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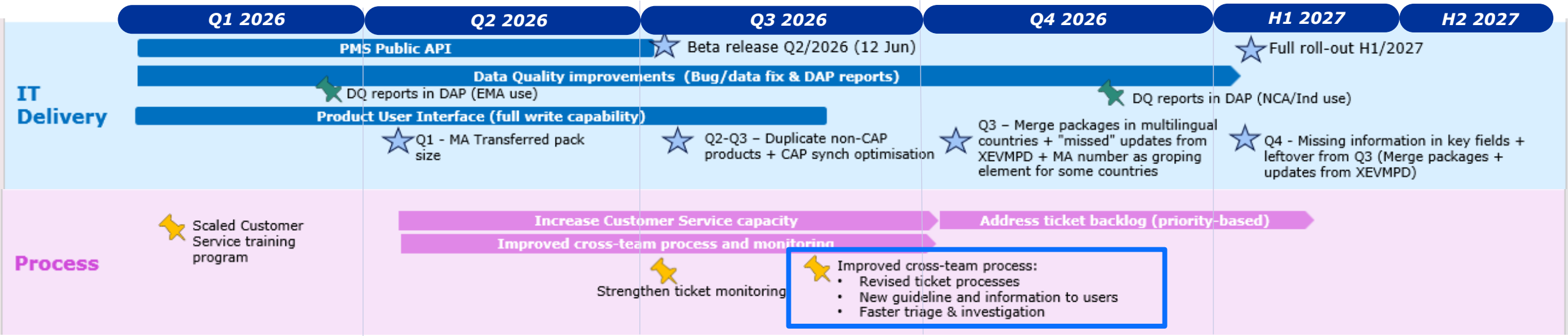

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Guideline and information to users

- Clarify how best to submit tickets based on the type of issues
- Explain ticket prioritisation and handling/resolution process

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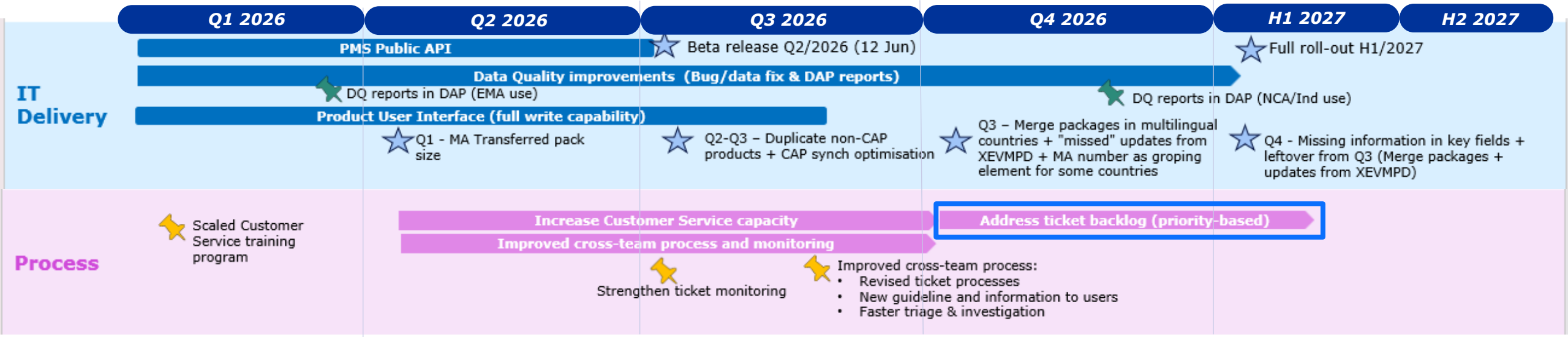

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Address ticket backlog

- Close and inform users of resolved tickets
- Resolve old tickets
- Explain tickets put on hold - clarify priorities and expected resolution for users

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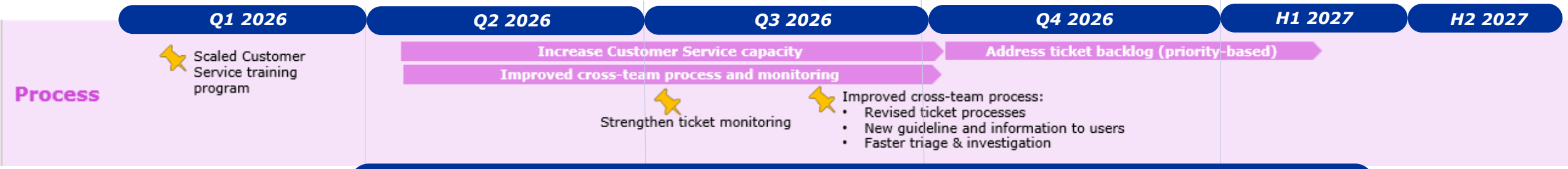

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Resulting in the following improvements:

Q1

- Prompt investigation and improved triage

Q2

- Strengthen ticket monitoring

Q3

- Increased customer service capacity
- Revised ticket processes
- Faster triage & investigations

Q4

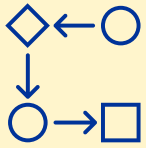
- Address ticket backlog

Data Quality incidents and ticket handling

Focused Data Quality: Prioritising High-Impact enhancements for Critical Use Cases

*Data quality efforts focus on **resolving high-impact issues** (such as duplicate, missing products and packages) that directly affect key regulatory and operational processes.*

*Actions are **prioritised around critical use cases** and the **specific data elements they rely on.***



Priority use cases

The main priority use cases being supported by product data are:

- **Shortages** monitoring
- NPL related activities such as vulnerability assessment
- Web-based **variation eAF**
- **PSURs**

Priority fields

Overall, remediation targets the **PMS data fields with the greatest regulatory and operational impact** to ensure effective and efficient processes.

- Identifiers
- Product full name
- Pharmaceutical dose form
- ATC code
- Active substance & strength*
- Route of administration
- Marketing Authorisation Holder
- Marketing Authorisation information*
- Packages*
- Manufacturers data*

* Class of PMS data elements

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Data Quality incidents and ticket handling

Users can help reduce unnecessary workload by limiting submissions to relevant, prioritised incidents, enabling faster resolution of the most critical issues

Data Quality incidents and Ticket handling

To **ensure efficient handling** of data quality incidents, users should align ticket submissions with the following **prioritisation criteria:**

- **Priority findings:** missing critical products/packages > duplicate packages > missing/incorrect information on priority fields (auth status, MAH)
- **Volume of products:** Highest > lower number of impacted products
- **Do not open tickets for:** known issues not yet resolved (e.g.: duplicated products), not priority fields or not affecting procedures (e.g.: package description, regulators)

Tickets resolution

- Tickets will not be resolved individually as they come in, rather will be addressed **in phases/batches** following the established priority
- As a result, **non-priority tickets** may be placed on **hold** for extended periods

Contacting EMA: when to use ServiceNow or AskEMA

Tool	Purpose	Use When…	Who Responds?	Access
ServiceNow	Support for **PMS-related topics**, including incidents, requests, and project-related questions	Your question or issue concerns **PMS**. As PMS is a **living IT project** that continues to evolve, all PMS-related requests should be submitted through ServiceNow.	The dedicated **PMS support team** monitors, tracks, and coordinates requests with other project teams when required to ensure timely resolution.	 ServiceNow link
AskEMA	Business questions related to specific **EMA business activities** (ie. Access to documents)	Your question relates to specific **EMA business processes, regulatory activities,** and is **not PMS-specific**.	Responses are provided directly by **EMA Officials,** including exceptionally PMS Product Owners.	 AskEMA link

Note: PMS Product Owners are **temporarily, and exceptionally** handling PMS-related requests submitted via AskEMA. Please use **ServiceNow** for all PMS-related requests.

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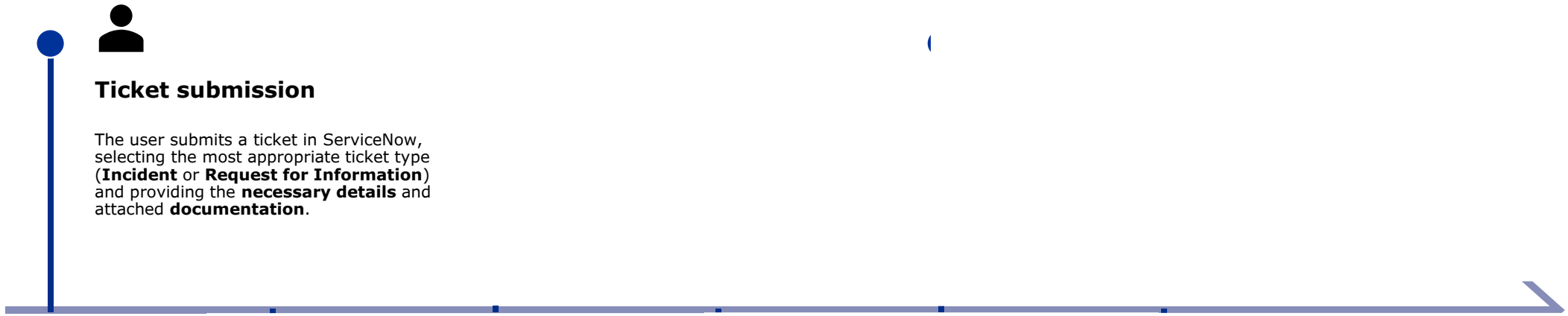
High-level overview of the PMS ServiceNow process



Ticket submission

The user submits a ticket in ServiceNow, selecting the most appropriate ticket type (**Incident** or **Request for Information**) and providing the **necessary details** and attached **documentation**.

Note: Resolution of some incidents may require coordination with multiple PMS project teams before the ticket can be closed.

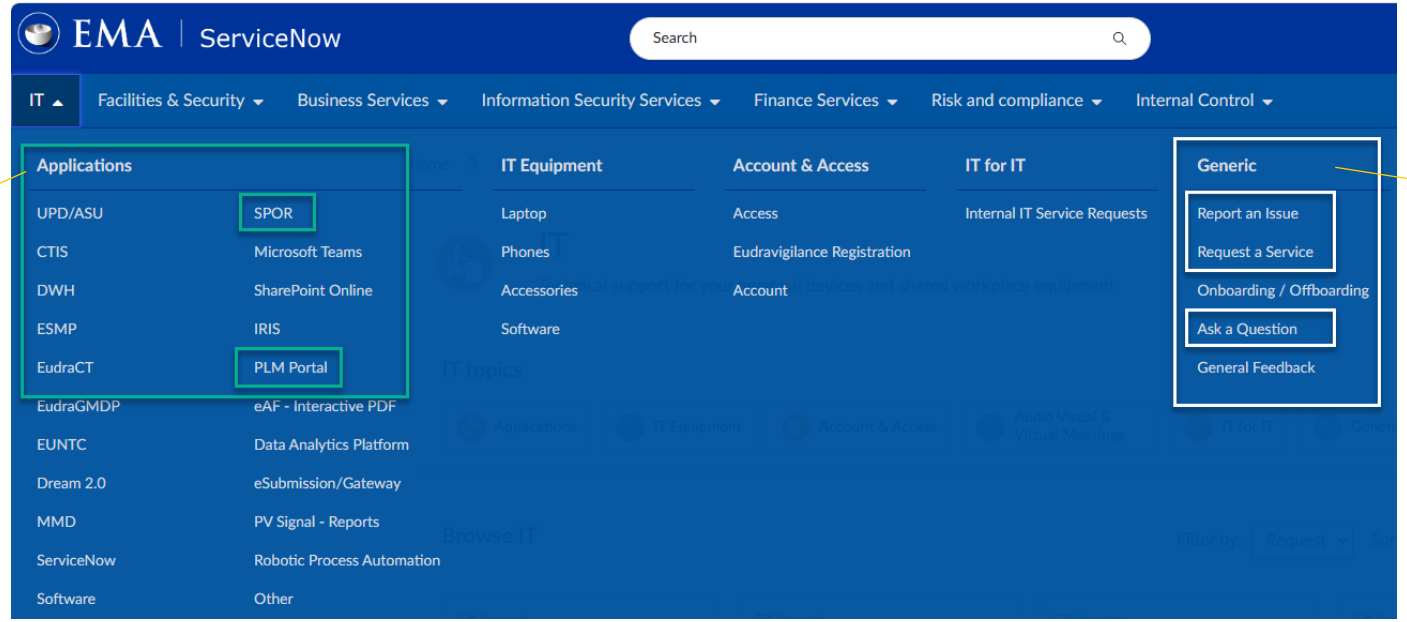
PMS ServiceNow ticket types

Step 1 – Select the relevant application/service in SNOW

Identify the application or service your request relates to.

- **PLM** – For questions, issues, or requests related to the PMS PUI Product Lifecycle Management (PLM) service.
- **SPOR** – For questions, issues, or requests related to pure PMS and PMS API service.

Recommended
(Tool-specific; few steps only)

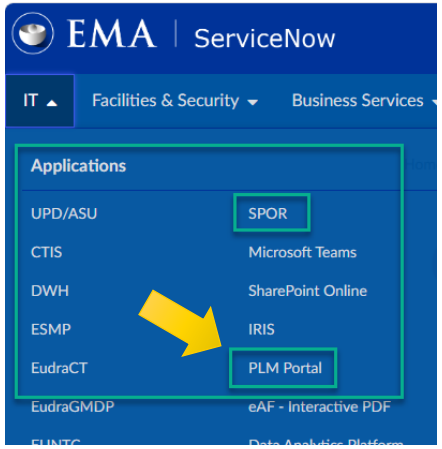


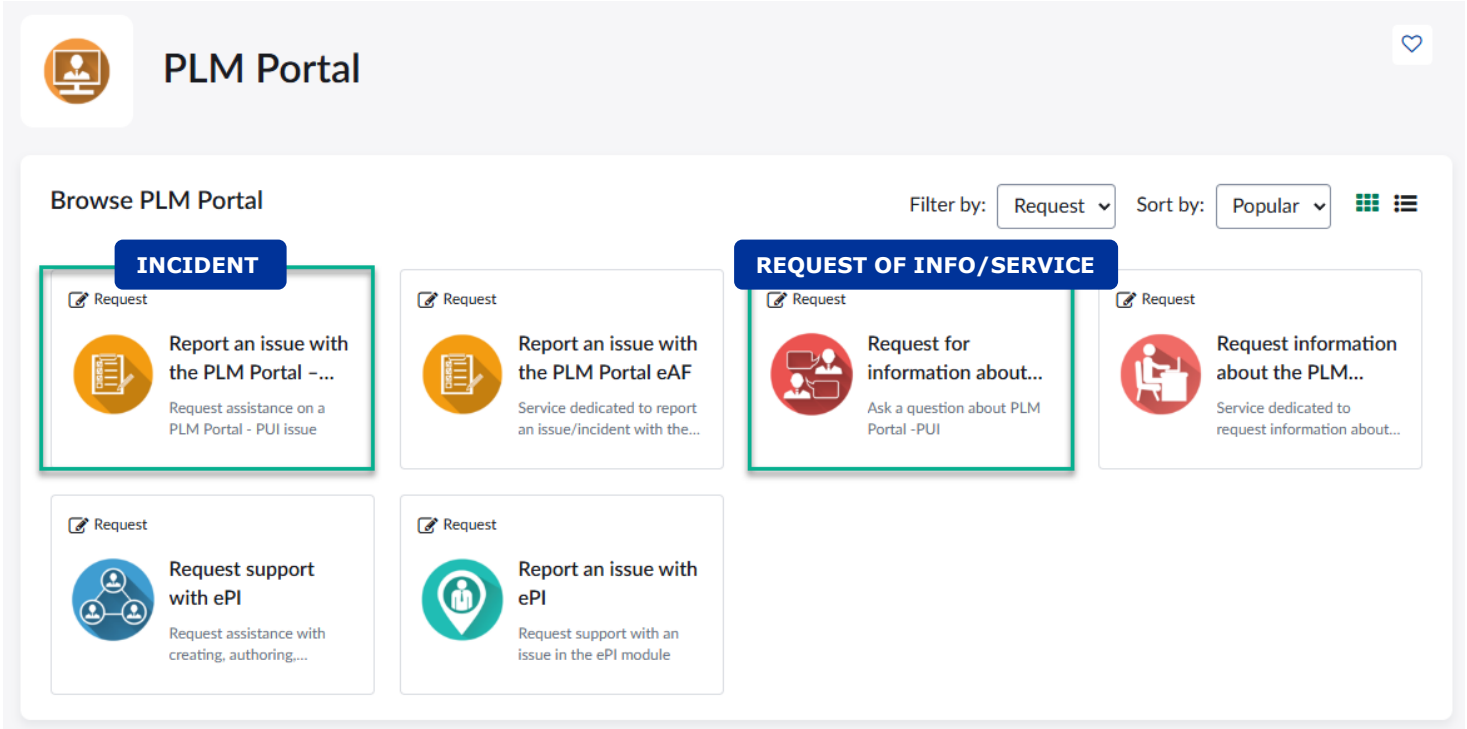
Alternative
(Highly generic; more steps)

PMS ServiceNow ticket types: when to use each

Step 2 – Select the appropriate ticket type

Ticket Type	When to Use It
Incident	Report a malfunction, system error, unexpected behaviour, or service disruption requiring investigation and resolution.
Request for Information	Request clarification, guidance, or information on the use of a PMS application or service.
Service Request	Request a standard service, such as access, configuration, or another predefined support service.





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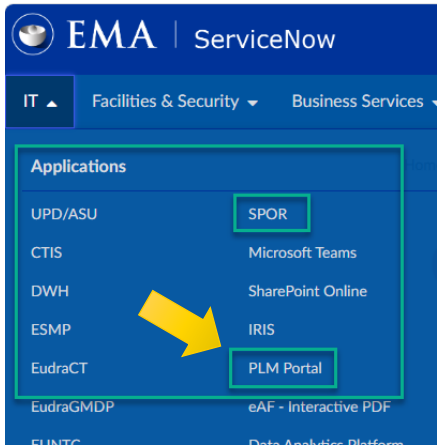
PMS ServiceNow ticket types: when to use each



Request for information about PLM Portal - PMS PUI

Ask a question about PLM Portal -PUI

Create a ticket for the question you have. Please provide as much detail as possible (incl.step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

* Indicate required information

* Raise this request on behalf of

Veronica Lipucci Di Paola

* Subject

* Description

* Problem area

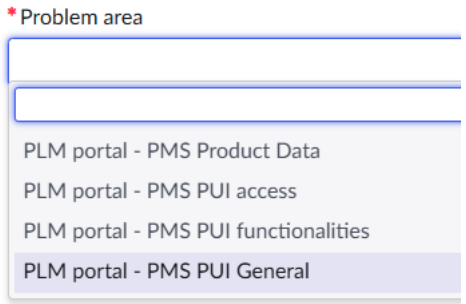
Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you NOT to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the Terms of use.

- **PLM portal – PMS PUI General** (topics covering multiple aspects and/or general nature)
- **PLM portal – PMS Product Data** (issues and questions with the product data as exposed/published in PUI)
- **PLM portal – PMS PUI access** (issues and questions on the access to PUI)
- **PLM portal – PMS PUI functionalities** (issues/discrepancies/errors with capabilities, i.e. filtering, exporting, sorting, searching, etc.)



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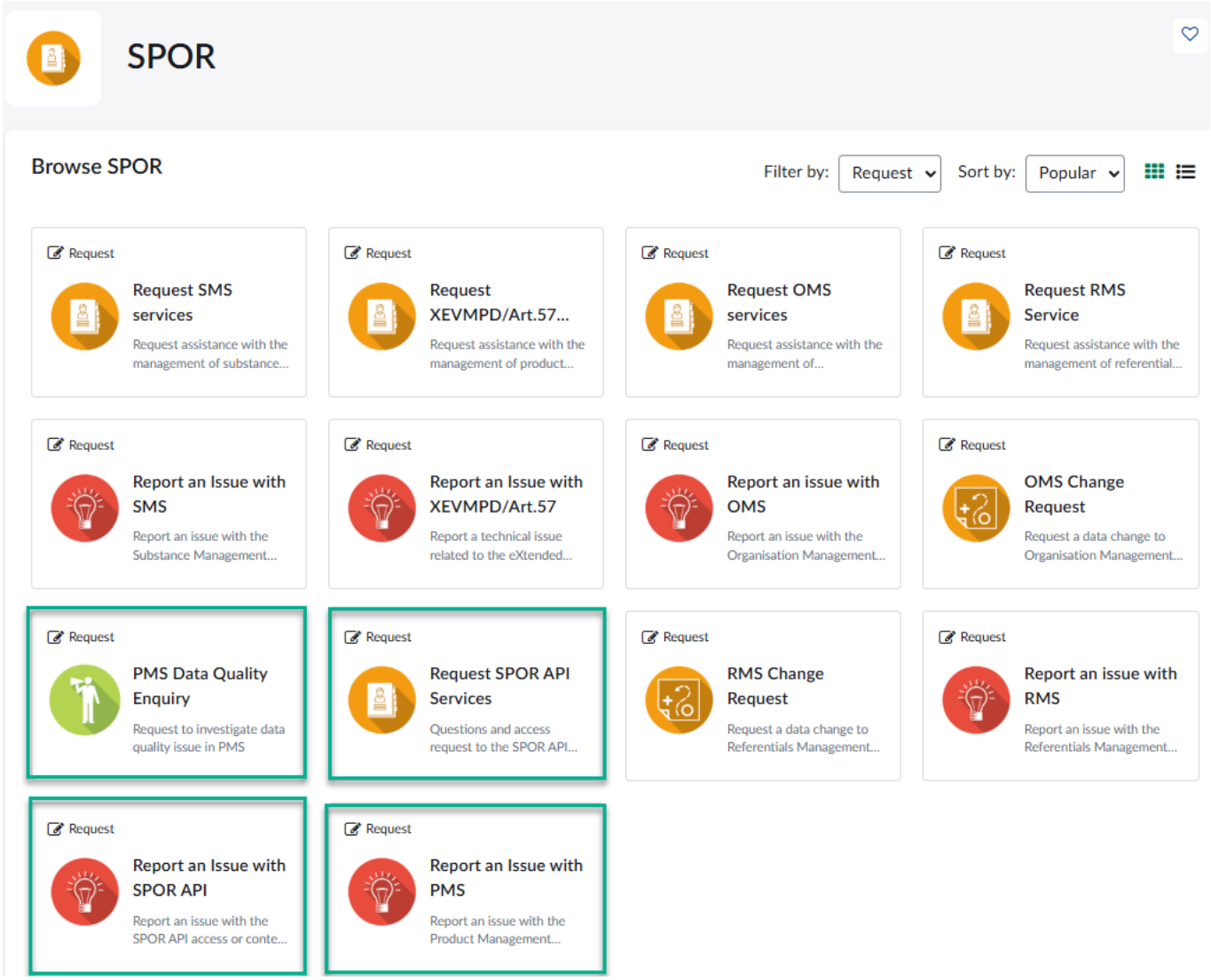
PMS ServiceNow ticket types: when to use each



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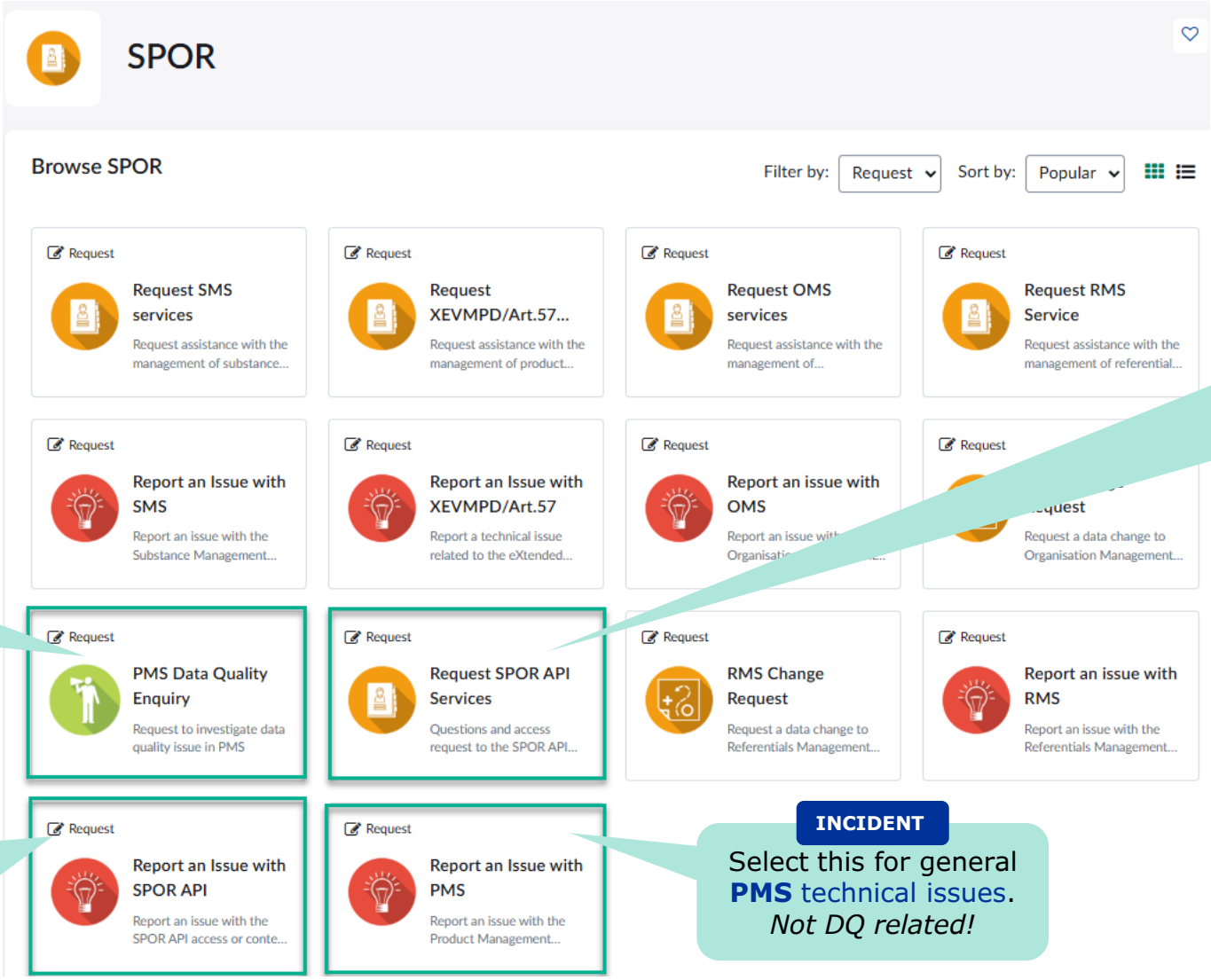
PMS ServiceNow ticket types: when to use each



REQUEST OF INFO/SERVICE

Select this to report pure **PMS Data Quality findings** in API or PUI

INCIDENT

Select this to notify a **PMS API**-related **technical issue** and specify the type of environment (Public PROD, Restricted UAT/PROD). *Not DQ related!*

INCIDENT

Select this for general **PMS** technical issues. *Not DQ related!*

REQUEST OF INFO/SERVICE

Select this to ask a **PMS API**-related **question** or a **service** (ie. renewal of secret credentials*) and specify the type of environment (Public PROD, Restricted UAT/PROD).

***Do not submit requests for initial PMS API secret credentials via this form.** Initial secret credentials are automatically generated and released through the IAM workflow.

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What happens after you submit a PMS ticket?

Initial Triage (1st/2nd Level Support)

The support team reviews the ticket, validates the information provided, assigns the appropriate priority and categorisation, and resolves the request where possible.

Feedback

User Feedback (if required)*

If additional information is needed from the requester, the ticket is placed **On Hold** until the requested feedback is received. Processing resumes once the information is provided.

Escalation to PMS 3rd Level Support

If further expertise is required, the ticket is assigned to the **PMS Business Support** team for detailed assessment and handling.

PMS specific **labels** are applied to categorise the tickets.

Investigation and Resolution

Where needed, the team coordinates with technical experts the relevant data fixes. The ticket is placed **On Hold** until feedback is provided, however routine updates are shared.*

Resolution and Closure

Once the issue is resolved or the requested information has been provided, the ticket is closed and the user is notified.

Resolution SLA depends on the complexity of the required data fix (if cross-platform) and the assigned priority level.

Feedback

Collaboration with other EMA project teams & Experts

When a notified finding or question has an impact on other EMA systems/projects, the PMS Business Support team may request **technical or business input** from the relevant Subject Matter Experts (SMEs) to support the investigation and resolution of the ticket.

The PMS Business Support team primarily collaborates with the following project teams:

- eAF
- ePI
- IRIS
- XEVMPD
- PMS API
- SMS
- OMS
- RMS
- SIAMED
- ESMP

Type of request	75% of requests	90% of requests
Incidents	Resolved within 5 working days.	Resolved within 10 working days.
Requests	Resolved within 5 working days.	Resolved within 10 working days.
Questions	Resolved within 22 working days	Resolved within 44 working days

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Q&A

30’

- **Join Slido.com** using this code **#ProductDQ** or scanning the QR code
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

slido

Please fill in the feedback survey

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ⓘ Start presenting to display the poll results on this slide.

EMA

Upcoming Q&A clinics

Q&A clinics on PMS PUI and API

- **23 July 2026** (9:30 – 10:30 CEST): Event page
- **Other dates** (9:30 – 10:30): 10 Sep, 24 Sep, 8 Oct, 22 Oct, 12 Nov, 26 Nov, 10 Dec → *registration available on EMA corporate website!*

Q&A Clinics on SOR

- **9 Sept 2026** (15:30 – 16:00 CEST): Event page
- **Other dates** (15:30 – 16:00): 7 Oct, 11 Nov, 9 Dec → *registration available on EMA corporate website!*

Q&A Clinics on XEVMPD

- **10 Sep 2026** (15:00 – 16:00 CEST): Event page
- **New dates for 2026** (15:00 – 16:00): 8 Oct, 12 Nov, 10 Dec → *registration available on EMA corporate website!*

PMS Progresses | How to stay informed

PMS News page

Check:

- News
- Events announcements
- Downtime comms

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

PMS webinars

- **Q&A Clinics** to answer users' questions
- **Targeted training sessions** on PMS systems' use

Check EMA's Website Events Pages (when also targeting Industry), EU-NTC (for Network only)

PMS FAQ Document

- Check FAQs on PMS (Document)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 17 Sep 2026

Announced via EMA's Website Events Pages - broadcast live

PMS Web Page

Find:

- PMS overview
- EU Implementation Guide

Check for general info on PMS

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SCIENCE MEDICINES HEALTH

Thank you

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