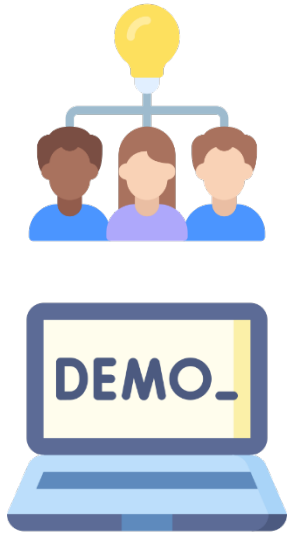
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

System Demo Q2-2024

26/06/2024

Public System Demo



Welcome/Introduction

Jean-Michel Becar, *Head of Portfolio Management Office, EMA*

*Please note that **this session is being live streamed.***
It is being recorded** and **will be made available** through the **EMA Corporate Website

*At certain points throughout the meeting, 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.*

System Demo

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Is a major part of the **transparency goal** of the Agency's new governance: lean and agile.

Shows an integrated view on what has been built in the past 3 months (Planning Interval (PI)).

Is an opportunity for the audience to **give instant feedback** to the Agency's development teams to build the right solution.

Is recorded and published on the EMA **Corporate website**.

Agenda

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1 **Welcome / Introduction**
09:00 – 09:05
- ***Jean-Michel Becar,*** *Head of Portfolio Management Office, EMA*

Managing the agency

2 **New Fee Regulation (NFR)**
09:05 – 09:25
- ***Paola Samassa,*** *Product Owner for NFR, EMA*
- ***Emmanouil Antonakis****, Scrum Master for NFR, EMA*

Monitoring Value Stream

3 **European Shortage Monitoring Platform**
09:25 – 10:05
- ***Sofia Zastavnik,*** *Product Owner for ESMP, EMA*

4 **Antimicrobial Sales and Use (ASU)**
10:05 – 10:20
- ***Anastasia Pickford,*** *Product Owner for ASU, EMA*

5 **Veterinary Union Pharmacovigilance Database (UPhV)**
10:20 – 10:35
- ***Laura Descalzo,*** *Product Owner for UPhV, EMA*

10 min BREAK

Agenda

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Product Lifecycle Management Value Stream

6 Union Product Database (UPD)
10:45 – 11:05
- ***Beyhan Mustafov,*** *Product Owner for UPD, EMA*

7 Electronic Application Form (eAF)
11:05 – 11:25
- ***Kristiina Puusaari,*** *Product Owner for eAF, EMA*

8 Product Management Service (PMS)
11:25 – 11:45
- ***Marcos Fernandez Gomez,*** *Product Owner for PMS, EMA*

9 Product User Interface (UI)
11:45 – 12:15
- ***Veronica Lipucci Di Paola,*** *Product Owner for PUI, EMA*

10 min BREAK

10 electronic Product Information (ePI)
12:25 – 12:45
- ***Elizabeth Scanlan,*** *Product Owner for ePI, EMA*

11 Regulatory Procedure Management (RPM)
12:45 – 13:15
- ***Madalina Duta-Mare,*** *Product Owner for RPM, EMA*
- ***Sara Santos,*** *Subject Matter Expert for RPM, EMA*

Managing the agency

12 Experts Management Tool (EMT)
13:15 – 13:30
- ***Michael Vogl,*** *Product Owner for EMT, EMA*

13 Closing remarks
13:30
- ***Jean-Michel Becar***

How to give feedback & ask questions

What is this system demo for?

1. show system features developed over the past 3 months
2. check progress in achieving the goals of the system
3. obtain feedback from stakeholders to build the right solution

How can you interact with this system demo?

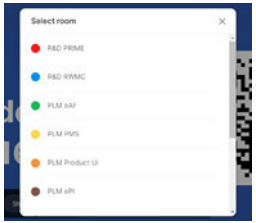
Option 1 – Slido Q&A

- Questions and answers are public
- You can upvote questions
- Top questions answered verbally, time allowing
- Questions & available answers published on event page

Option 2 – Slido short feedback poll

- **Not public**
- Remains open until 10th July
- Please identify yourself
- Specific suggestions and feedback about your priorities

Step 1 - Go to slido.com



Step 2 – Choose/switch to the room for the right product

Step 3 - Choose Q&A or Polls as appropriate

Value Streams

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Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Owner: Mireia Castillon / Ieva Lobaciute (ad interim)

Manager: Rob Hopping

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Owner: Steven Le Meur

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Owner: Anne-Marie van Nederkassel

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Capabilities to monitor availability and safety of products

Owner: Pedro Pina Ferreira

Manager: Pedro Oliveira

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Owner: Leonidas Tertipis

Manager: Pedro Rodriguez/Christian Drescher

R&D Value Stream - Go-Live milestones

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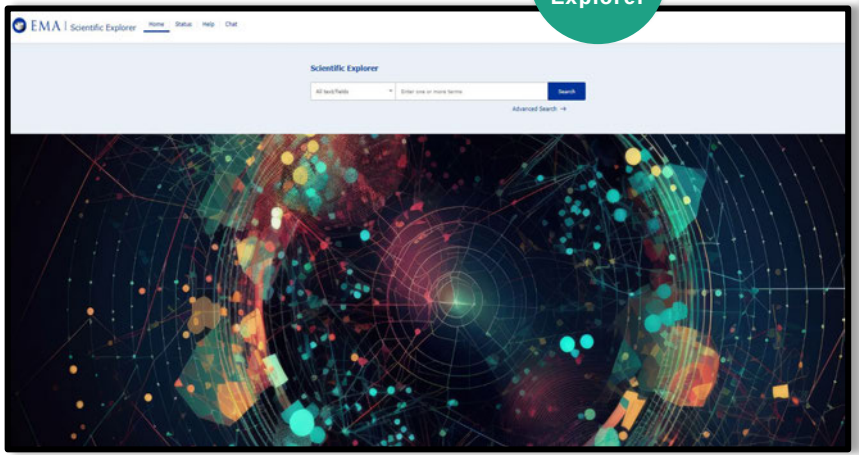
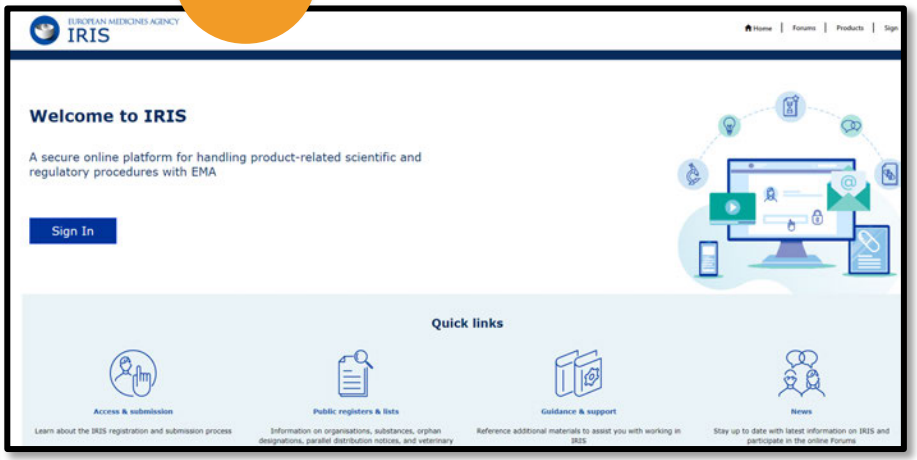
Scientific Explorer



- AI enabled scientific information search tool for EU regulators
- Integrated in the HMA-EMA joint Big Data Steering Group workplan
- First version focuses on Scientific Advice letters
- Key users: EMA and Scientific Advice Working Parties (SAWP), Committee for Medicinal Products for Human Use (CHMP), Committee for Advanced Therapies (CAT) and Committee for Orphan Medicinal Products (COMP)

Go-live 04 March 2024

Paediatrics processes



- Scope: Paediatric Investigation Plan submission, modification, compliance check, product-specific waiver, annual reports
- Stakeholder engagement:
- Establishment of PDCO change champions group, and
- Industry volunteers' group

Go-live 03 June 2024

Value Streams

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Managing the agency VS | New Fee Regulation

Paola Samassa, *Product Owner for EPIC 2 NFR, EMA*

Emmanouil Antonakis*, Scrum Master for NFR, EMA*

New fee regulation effective from 1st January 2025

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Key milestones of the regulatory review cycle

1995-2010

Entry into force of the Fee regulation
First review of fee system **put on-hold**

2015 onwards

EC resumed work (with NCA+EMA) on **review of the EMA fee system**

2022

EC published its **proposal for a new fee regulation**

2024

Adoption of new fee Regulation (EU) 2024/568 effective **1st January 2025**

Principles and objectives* for a new EMA fee system

- **Harmonisation:** establishing a **single framework** for a **streamlined fee system** of the Agency;
- **Flexibility:** introducing **regulatory flexibility**, adjusting fee levels and associated costs, **solid frame for innovation** in the pharmaceutical sector e.g. **incentives** for SMEs and entities not engaged in economic activities, pandemic situation, immunological veterinary products, etc;
- **Alignment:** **align fees** and **remuneration to National Competent Authorities** with actual costs to carry out the activities (**cost-based**); align with the provisions of the Veterinary Medicinal Products Regulation and reflect the latest revision of the EMA Founding Regulation
- **Sustainability:** providing a **sound financial basis** for the Agency and the **Network's operations**, for the **protection of public and animal health;**

** The source of these objectives is the EC legal proposal*

Key changes to Orphan Designation and Paediatrics processes

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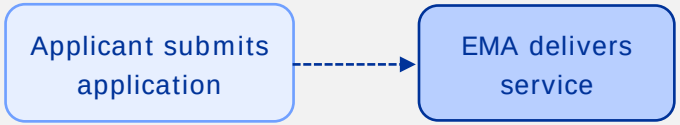
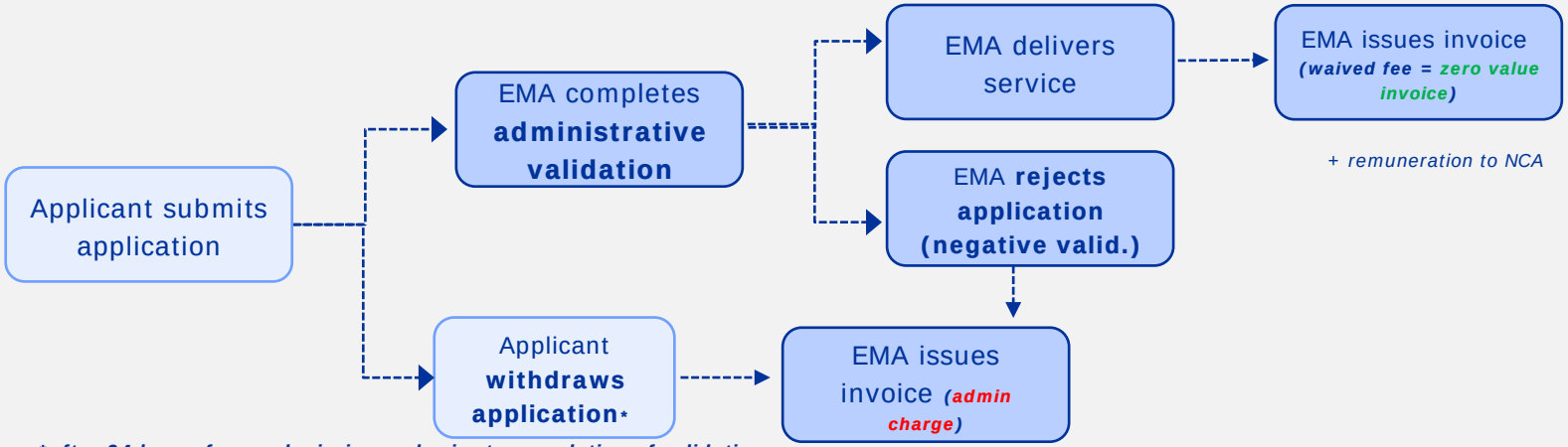
Current: no fees or charges are applicable to these services



Future: the fee is fully waived but administrative charges will apply under certain conditions



****after 24 hours from submission and prior to completion of validation***

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New payment process for Sc. Advice, Certificates and Parallel Distribution

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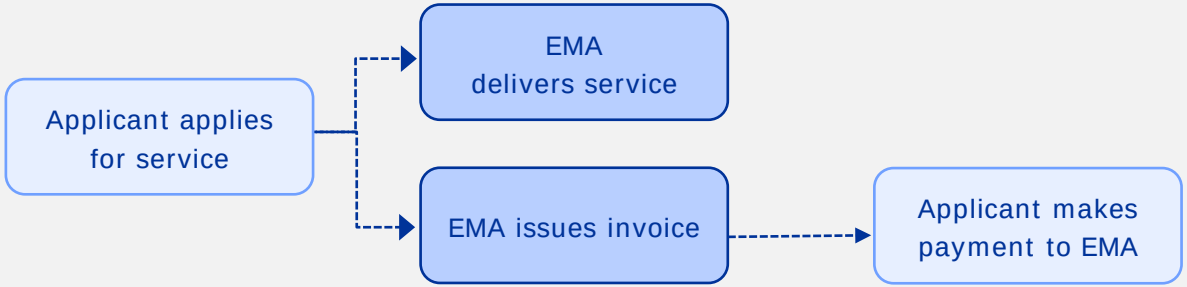
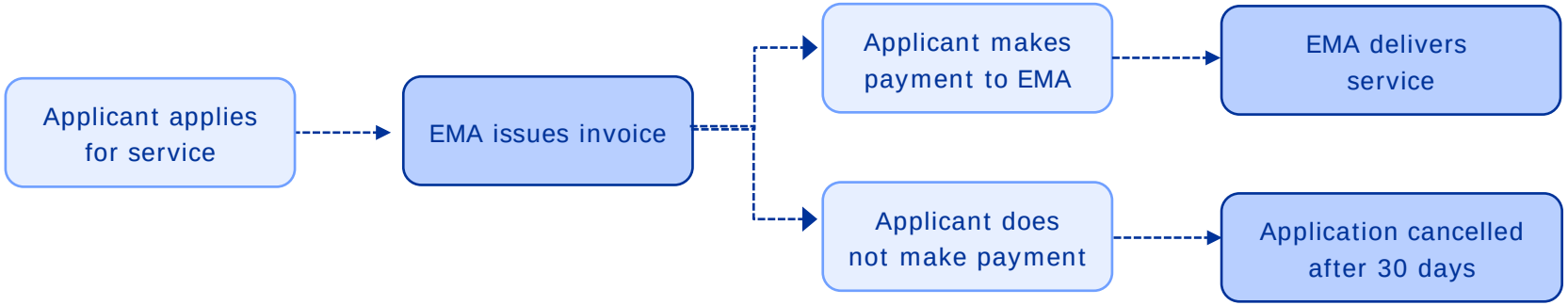
Current: provision of service is independent from fee or charge having been paid



Future: provision of service only after fee or charge has been paid in its entirety



Timeline for IT preparation for implementation

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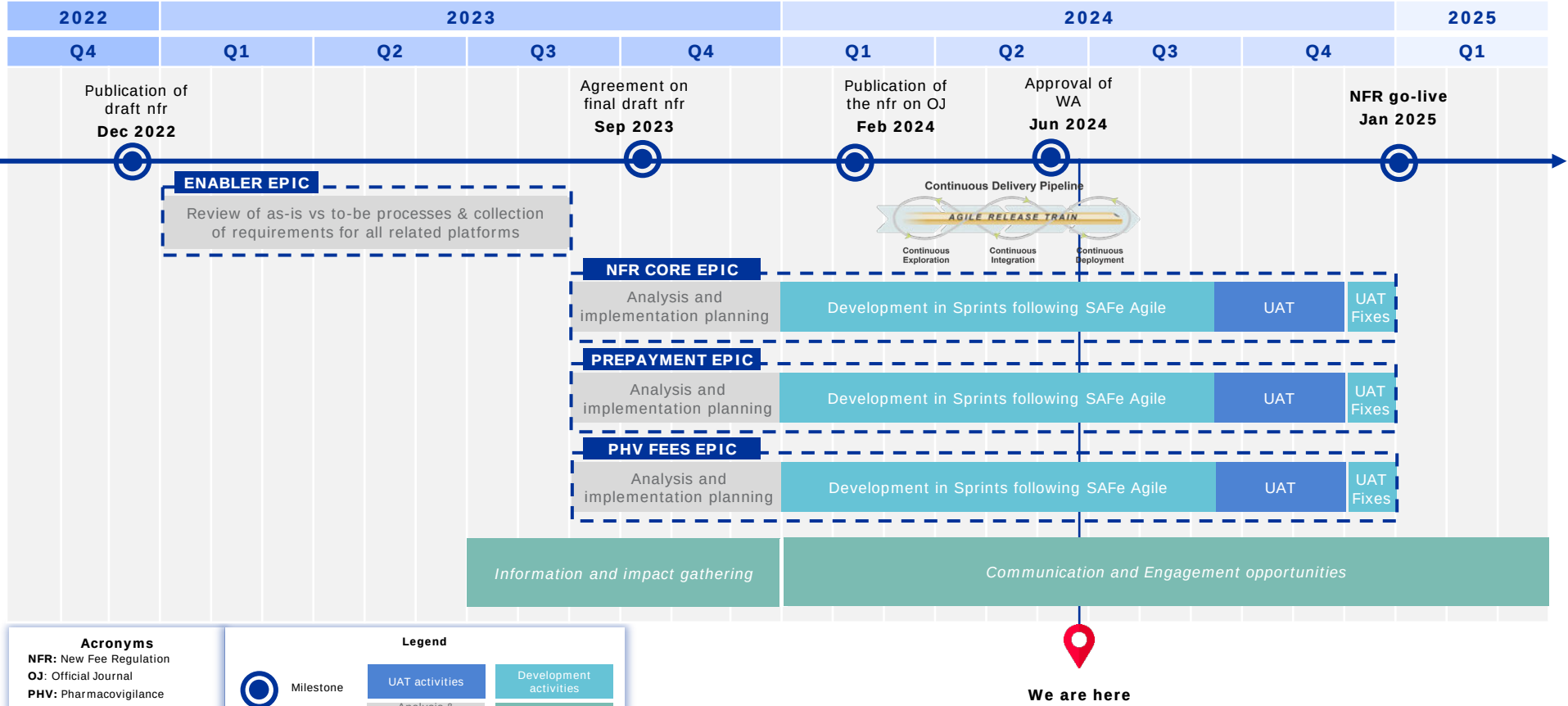

Acronyms

NFR: New Fee Regulation
OJ: Official Journal
PHV: Pharmacovigilance
SAFe: Scaled Agile Framework
UAT: User Acceptance Testing
WA: Working Arrangements

Legend

Milestone

UAT activities

Development activities

Analysis & preparatory activities

Change Mgmt activities

PI achievements Q2/2024

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Apr May Jun

PI ACHIEVEMENTS – Q2 2024

STATUS

- 1 - Terminated integration between SPOR for the new interface.
- 2- Implementation of the first set of fees (Orphan Designation, Parallel Distribution, and pre-submission)
- 3 - Conducted a comprehensive technical analysis and integration with IRIS Core to the Interface for propagating Fee details to the Financial and Accounting application.
- 4 - Established the foundational back-end technical infrastructure, including interfaces and connections with new systems.
- 5 - Achieved full development and integration of Case Management for Referrals, ensuring seamless workflow processes.
- Change Management:
- 6 – SMEs partly trained & continuously supporting the development and change management
- 7 - H and V stakeholders made aware of the changes brought about NFR
- 8 - Industry and Network: further details of the upcoming changes provided during meetings

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Industry and Network stakeholders' engagement opportunities

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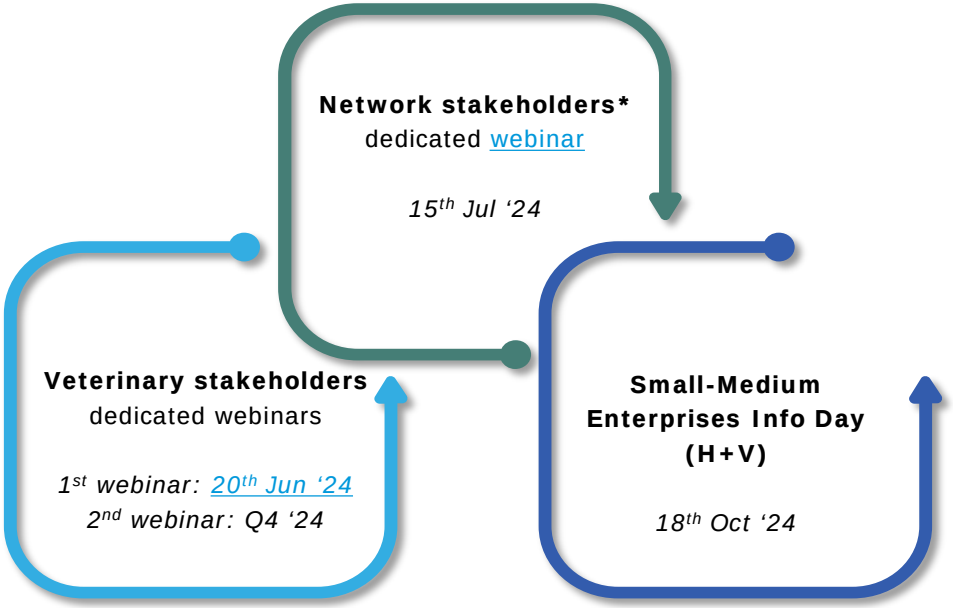

*Invitations will be sent out in the next couple of weeks, registration will be available via EU-NTC.

Q&A For any questions, please email NFR@ema.europa.eu

Value Streams

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Monitoring VS | European Shortages Monitoring Platform (ESMP)

Sofia Zastavnik, *Product Owner for ESMP, EMA*

The European Shortages Monitoring Platform (ESMP)

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Data collection

- Shortage information
- Supply and demand of medicines
- i-SPOC Registration

Analysis & Reporting

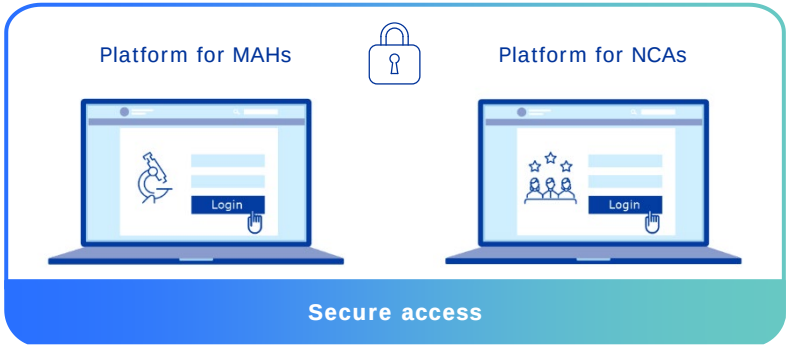
- Matching supply & demand
- Reporting findings and results
- Public reports

Shortages management

- Maintain critical medicinal product lists
- Evaluate and manage medicine shortages

Data integration

- EMA data management (SPOR, IAM, IRIS integration)
- Interoperability with NCA and industry systems



Development timeline

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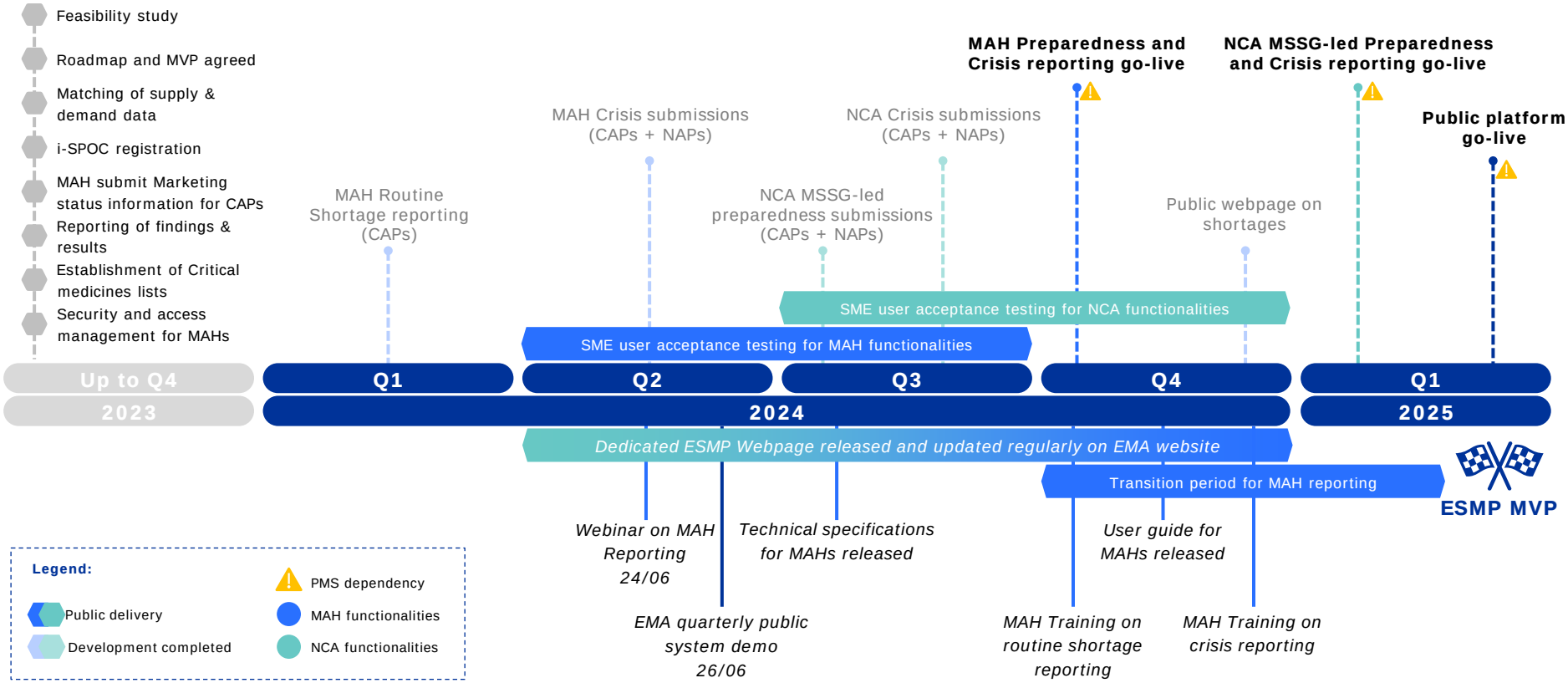

User acceptance testing: initial results

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Objective	Ensure platform meets user requirements, functions correctly, is user-friendly, and fulfils user expectations
Duration	22 – 30 April 2024
Participants	Industry subject matter experts (SMEs)

Functionalities and items tested

- **Routine shortage** reporting
- **Crisis** reporting
- Marketing status CAP (link to IRIS portal)
- Availability Information
- Alternative therapies
- My critical medicines pages

For all data submission flows:

- Submission history
- Generating and downloading pre-filled templates with products in scope of reporting requirements
- Data submission

- Implementation guide
- User guide

Positive feedback

- Appreciated **overall functionality** of the platform
- User-friendliness of the ESMP **user interface** and ease of navigation
- No issues reported about **data display**

Areas for improvement

- **Complex reporting templates** and **conditionality rules for** data submission → **ACTION TO BE TAKEN**: refined reporting templates to reduce manual insertion of data (e.g., reduced no. of columns for shortage root cause, merged fields for shortage end date and expected end date)
- **Slow platform performance** → **ACTION TO BE TAKEN**: changes in mechanisms for data upload and processing, targeting largest and most comprehensive data submission flows to reduce long processing times
- **Overly comprehensive user guidance**, including instructions and technical specifications, difficulty accessing RMS lists and lack of clarity of some definitions → **ACTION TO BE TAKEN**: merged user, implementation guides and RMS lists within the same document, refinement of data element definitions with industry representatives

ESMP Essentials: summary of webinar for MAHs

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Objective	provide an overview of the ESMP and pharmaceutical industry reporting requirements through the platform
Duration	24 June, from 10:00 to 12:30 CEST
Target audience	Pharmaceutical industry, marketing authorisation holders of CAPs and NAPs

KEY TOPICS

ESSENTIALS

- EMA **shortage management** processes at EU/EEA level
- Overview of **ESMP vision, objectives, benefits**, components
- ESMP **milestones and dependencies** with other EMA products and MAH requirements

REPORTING

- **Reporting processes**: crisis, MSSG-led preparedness, routine reporting
- **Reporting requirements**: MAH requirements in crisis, MSSG-led preparedness, routine reporting
- **Data elements** in scope of reporting requirements to EMA through ESMP

Q&A session to gather doubts and concerns and address them

Please note that the webinar was broadcasted live, recorded, and the recording is available on the dedicated event page.

High level progress diagram

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Access Management

MAHs | NCAs | Public

Data collection

MAHs

Crisis / MSSG-led preparedness		Preparedness
User Interface	Alternative Therapies	User interface
Overview of critical medicines	Marketing status NAPs (DEMO.)	Routine shortage reporting CAPs
Marketing status CAPs	Manufacturing details, production plan CAPs (DEMO.)	
Availability of medicines	Production plan NAPs	

NCAs

Crisis	MSSG-led preparedness
User interface	User interface
Stock and supply	National demand
Patient estimation	
Medicine usage	

Analysis & Reporting

- Match supply and demand
- EMA dashboards and reports
- NCA dashboards and reports
- Public webpage

Shortages Management

- iSPOC registration
- Maintain lists of critical products
- Case management of CAP shortages

Data Integration

PMS integration (CAPs) | RMS integration | PMS integration (NAPs) | Interoperability

Completed | In Progress | Not Started

PMS : Product Management Services
RMS : References Management Services

ESMP features: Marketing status for NAPs

Marketing Status for NAPs in ESMP

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The ESMP aids crisis management and MSSG-led reporting by requiring marketing authorisation holders (MAHs) to accurately report and keep-to-date marketing status information for nationally authorised products (NAPs) for **products used for the management of a crisis**, or **products for which close monitoring is triggered by the MSSG**, ensuring proper management of availability and supply of those medicines.

Marketing status data on centrally authorised products (CAPs) will be automatically imported from IRIS and pre-populated within ESMP reporting templates where relevant. For NAPs, a **dedicated data submission flow** will be available in ESMP for products in scope of crisis and MSSG-led preparedness reporting.

Data Submission

- Marketing status for NAPs is requested directly in the ESMP
- Data is submitted via a standalone reporting data flow
- Submitted data is reflected in the ESMP and relevant templates

❖ Marketed or Temporarily Unavailable Products

- Products that are "Marketed" or "Temporarily Unavailable" in a particular country can have all other relevant information on the **availability and supply submitted** for crisis and MSSG-led reporting -> information on those products will be pre-populated in the relevant templates for MAHs to insert shortage information, forecast of supply, etc.

❖ Not Marketed or Never Marketed Products

- Products stated as "Not Marketed" or "Never Marketed" will not be eligible for further data collection in the ESMP
- Entries for these product and country combinations will not be pre-populated in other ESMP data submission templates (availability of medicines)

Platform view: marketing status NAPs

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- Preparedness (PHE, ME)
- Crisis (PHE, ME)

- My critical medicines
- Marketing status CAPs
- **Marketing status NAPs**
- Availability information
- Manufacturing information
- Alternative therapies

For the relevant **NAPs** in the scope of reporting requirements the platform will enable the MAHs to **submit the marketing status** data and show the data **previously submitted through the ESMP**, if applicable

To perform this submission, MAHs will:
1) Download a reporting template pre-filled with the relevant NAP product information
2) Compile and submit relevant information
3) Perform updates to keep information current

Marketing Status for NAPs – Product information & details

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- Preparedness (PHE, ME)
- Crisis (PHE, ME)

Product information (pre-populated from PMS)	*PMS ID (Packaged medicinal product)*
	Full product name
	Short product name
	Active substance
	Strength
	Pharmaceutical form
	Pack size
	Packaging
	PCID
	Country of authorisation
Marketing status details	Marketing status
	Date of planned permanent withdrawal
	Planned withdrawal comment

System Demo: let’s see it working!

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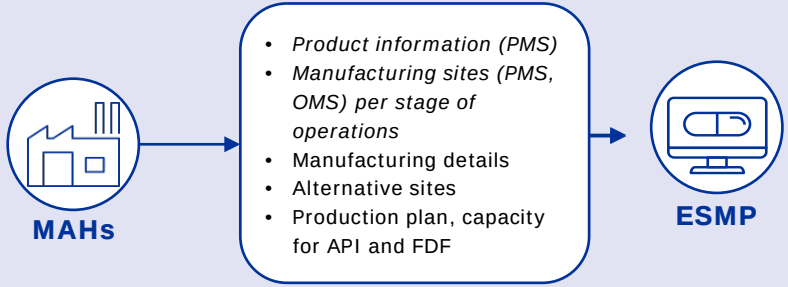
ESMP features: Manufacturing information for CAPs

Manufacturing information in ESMP - CAPs

The manufacturing information and production plan feature is designed to provide comprehensive insights into the **manufacturing details**, including the **production plan and capacity of centrally authorised products** (CAPs). This feature is crucial for estimating the quantity of products produced globally and for planning effective responses to shortages.



CAPs and NAPs

- **CAPs will be listed** alongside their manufacturing sites for all stages of manufacturing (since data is available in PMS)
- **for NAPs** information on manufacturing sites will be integrated into the ESMP once this data is submitted in PMS

Data Collection

- MAHs report on production methods (own factory or subcontracted) for each stage of manufacturing and alternative sites
- Submission of monthly production data and capacity as average and peak outputs for API and FDF

Output

Overview of quantities of active pharmaceutical ingredients and finished dose forms produced globally, with a view of average and peak amounts produced in non-crisis situations to estimate baseline production capacity

Platform view: manufacturing information

EUROPEAN MEDICINES AGENCY

- Preparedness (PHE, ME)
- Crisis (PHE, ME)

- My critical medicines
- Marketing status CAPs
- Marketing status NAPs
- Availability information
- **Manufacturing information**
- Alternative therapies

For medicinal products subject to crisis/MSSG-led preparedness monitoring through the ESMP MAHs need to report on **manufacturing methods** (own factory or subcontracted), alternative sites, **production plans** and **production capacity** (average and peak outputs) for the active substances and final dose form

To perform this data submission, MAHs will:

1) **Download a reporting template** pre-filled with the relevant CAP & NAP product information
   - **CAPs will be listed** alongside their manufacturing sites for all stages of production (data available in PMS)
   - **for NAPs** information on manufacturing sites will be integrated into the ESMP once this data is submitted in PMS
2) **Compile and submit** relevant information
3) **Perform updates** to keep information current at a **frequency defined by the MSSG**

Data elements: manufacturing information

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- Preparedness (PHE, ME)
- Crisis (PHE, ME)

Product information *(pre-filled from PMS)*	*PMS ID (Medicinal product)*
	Full product name
	Active substance
Organisation information *(pre-filled from PMS and OMS, currently available only for CAPs)*	*Organisation ID (Manufacturer)*
	Manufacturer
	Operation type ID
	Operation type
	Location ID (Manufacturer)
	City
	Country
Manufacturing details	Manufacturing site status (active/backup)
	Is the site a contract manufacturer? (yes/no)
Alternative sites	Alternative site Location ID
	Alternative site Country

	Unit of measurement (kg/units)
Production plan *(for API and FDF)*	Global monthly production plan - month 1
	Global monthly production plan – month 2
	Global monthly production plan – month 3
	Global monthly production plan – month 4
	Global monthly production plan – month 5
	Global monthly production plan – month 6
	Additional information on the production plan
Production capacity *(for API and FDF)*	Average global monthly production output of previous year
	Peak global monthly production output of previous year

*submission of manufacturing information for NAPs currently under refinement, changes possible

System Demo: let’s see it working!

slido # 9116064

Antimicrobial Sales and Use (ASU) Platform

Anastasia Pickford, *Product Owner for ASU, EMA*

The Antimicrobial Sales and Use (ASU) Platform

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Vision

A **reference European surveillance system** for EU/EEA member states to **submit data on sales and use of antimicrobials in animals**, enabling data intelligence to detect patterns and help develop **measures against antimicrobial resistance**, thus contributing towards the One Health goal of safeguarding animal and public health.

Regulation (EU) 2019/6 on VMPs – Article 57

Access management

- Provide a web interface for MSs to report, analyse and validate data with controlled access

Data collection

- Support harmonisation and data quality
- Avoid duplication of data input across systems
- Improve upon previous data collection system

Analysis & Reporting

- Support data analytics
- Enable publication of annual reports
- Provide Public interactive BI dashboard

Data analytics

- Provide comparable data at Union level
- Enable data intelligence to detect patterns
- Integrate with data from other sources

ASU Delivery timeline

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IT Development

First data call

Preparation of the first Report by the Agency

2023

Up to Q4

- Development of **web interface** and **Power BI application**.
- **Provide access** to MSs for testing purposes
- Work on **data quality**

2024

Q1

ASU Go-Live
29 January

Q2

30 June
Deadline for MSs to submit sales and animal population data

Q3

30 September
Deadline for MSs to submit use data (on cattle, pigs, chickens and turkeys)

Q4

31 December
Deadline for EMA to publish **second annual sales & use data report** (2024 data)

2025

Q1

31 March
Deadline for EMA to publish **first annual sales & use data report** (2023 data)

2026

MS to start collecting use data for other food-producing animal species

2029

MS to start collecting use data for all categories, incl. cats, dogs and fur animals)

Beyond 2030

30 June
Deadline for MSs to submit all data to EMA

31 December
Deadline for EMA to publish annual sales & use data report (data previous calendar year)

System Demo: let’s see it working!

slido # 9116064

Veterinary Union Pharmacovigilance Database (UPhV)

Laura Descalzo, *Product Owner for UPhV, EMA*

PI objectives & achievements Q2/2024

EUROPEAN MEDICINES AGENCY

Apr | May | June

PI ACHIEVEMENTS – Q2 2024

- **Improve efficiency of Duplicate detection tool and manual recoding tool by enhancing look and feel**
- **Add product grouping to “Adverse event overview” and “Line listing” dashboards to enhance analysis capability for MAHs**
- **Implementation of 'Trends' analysis on “Signal detection dashboard” at Product Grouping level to increase analysis power for NCAs and MAHs**
- **Integrate with IRIS variations process**

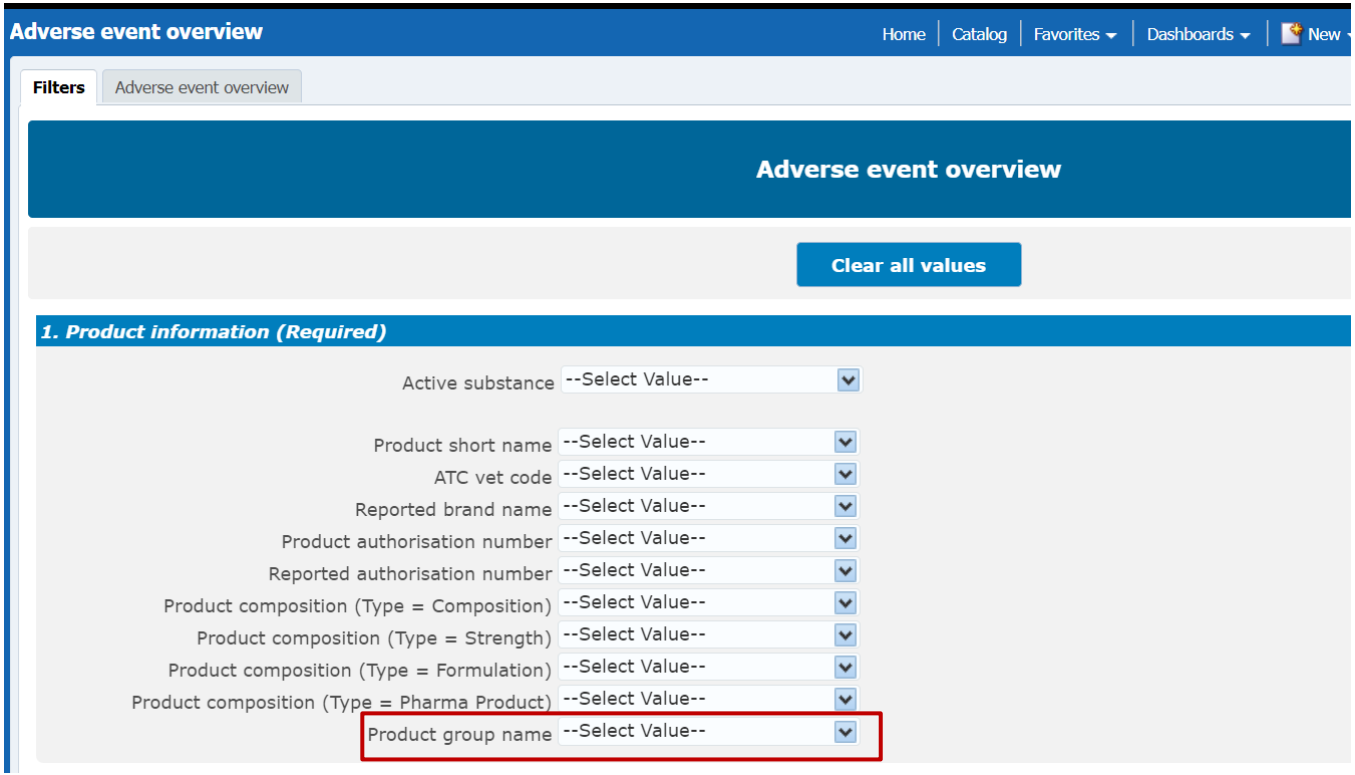
PI PLANS Q3 2024

- **Enhancements to Signalling dashboard and Trends analysis dashboard**
- **Precalculations at Product Group level in Signal detection dashboard**
- **Improvements to**
  - Duplicate management tool
  - Manual recoding tool

Q2 DEMO:

- Trends analysis dashboard
- Improvements in Duplicate Detection tool

DWH: Addition of Product group name in Adverse event overview



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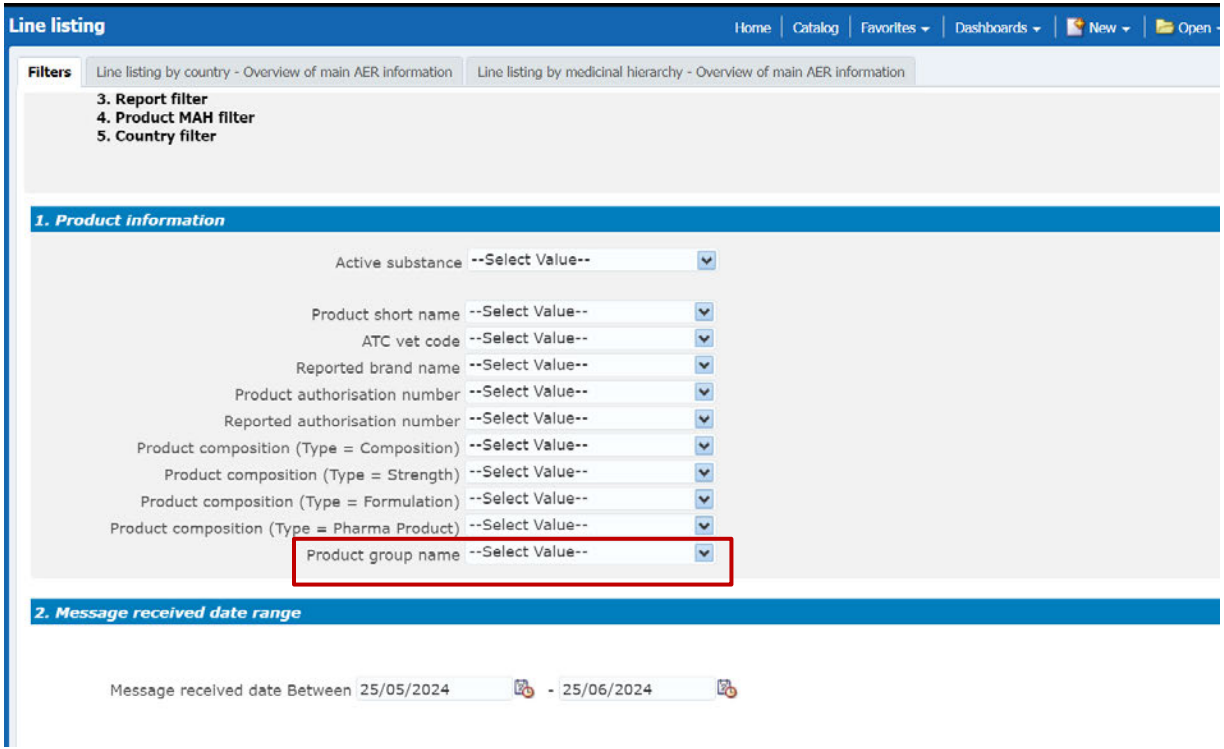
DWH: Addition of Product group name in Line listing



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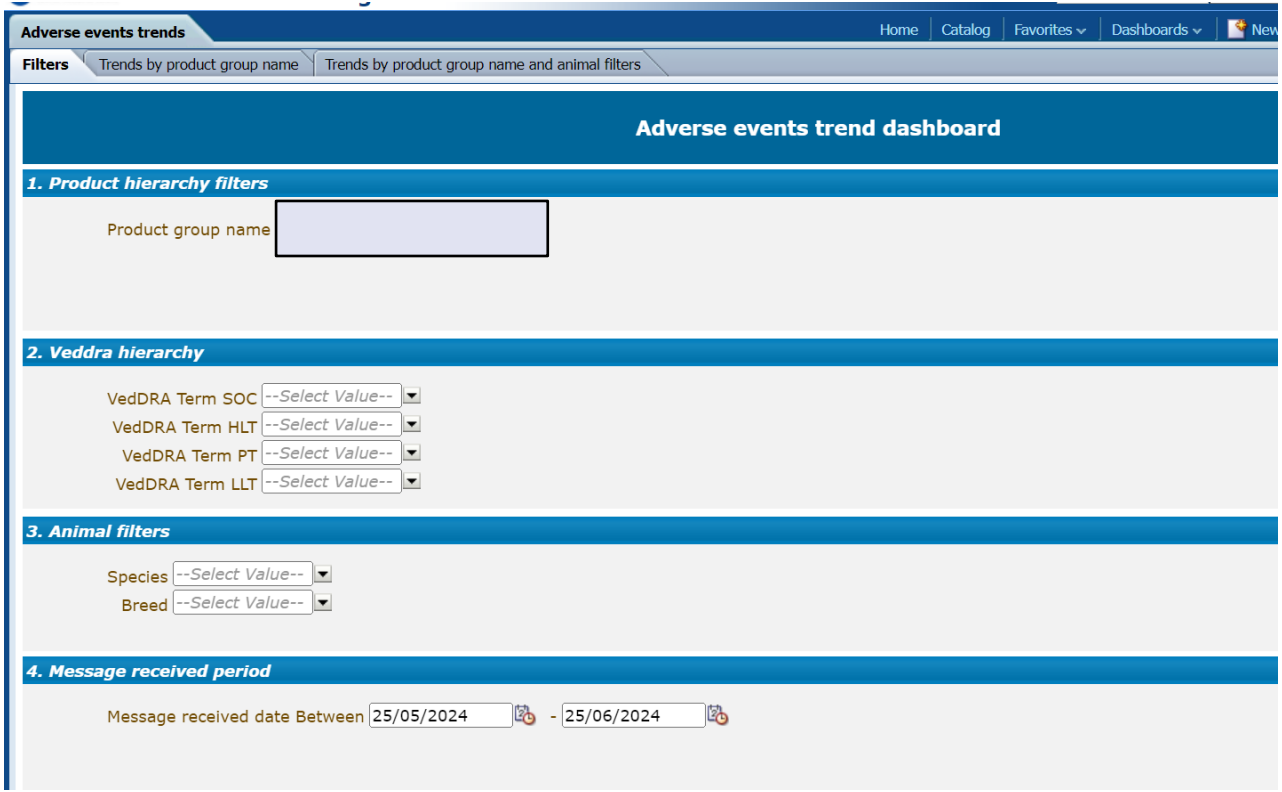
DWH: Adverse events trends dashboard



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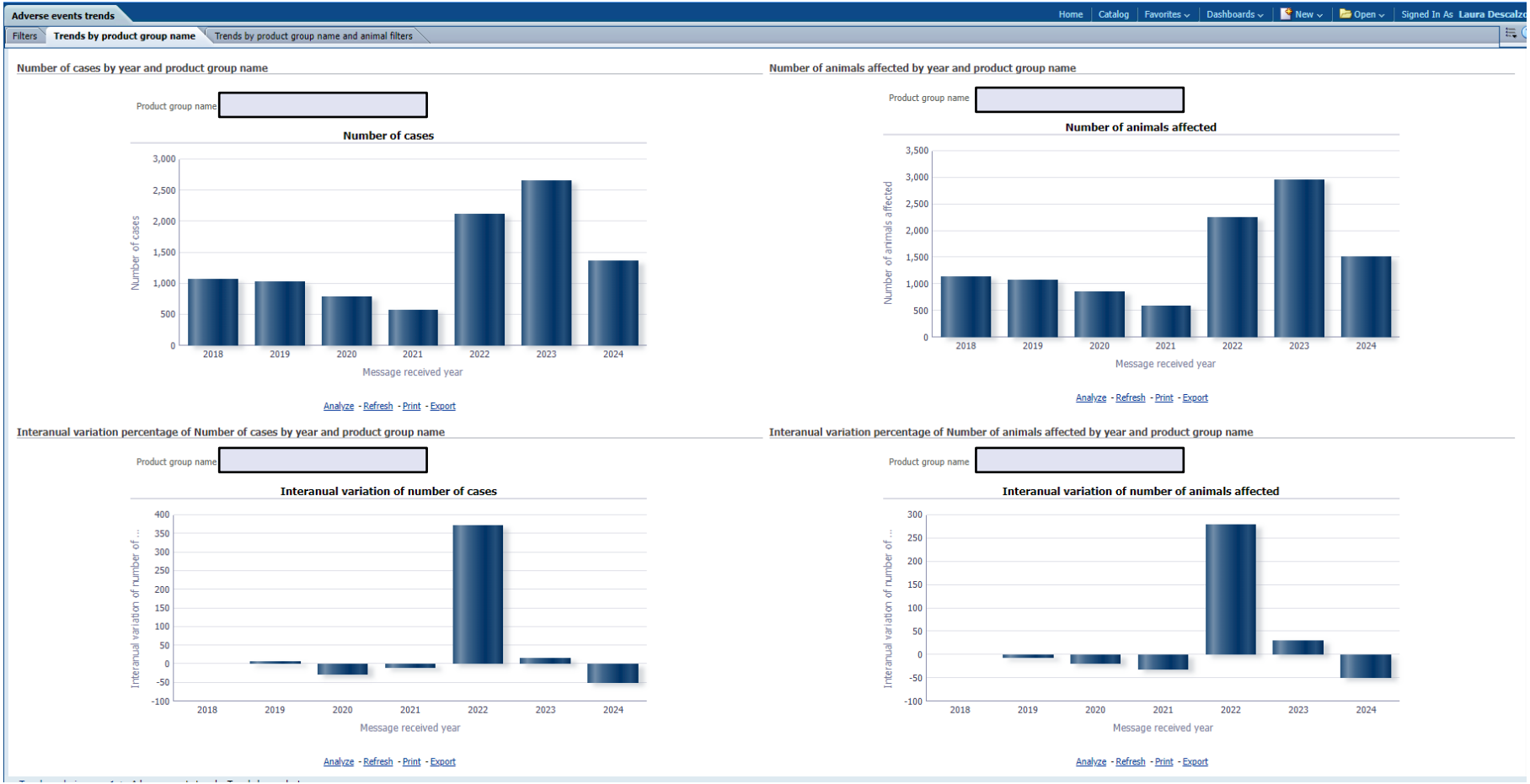
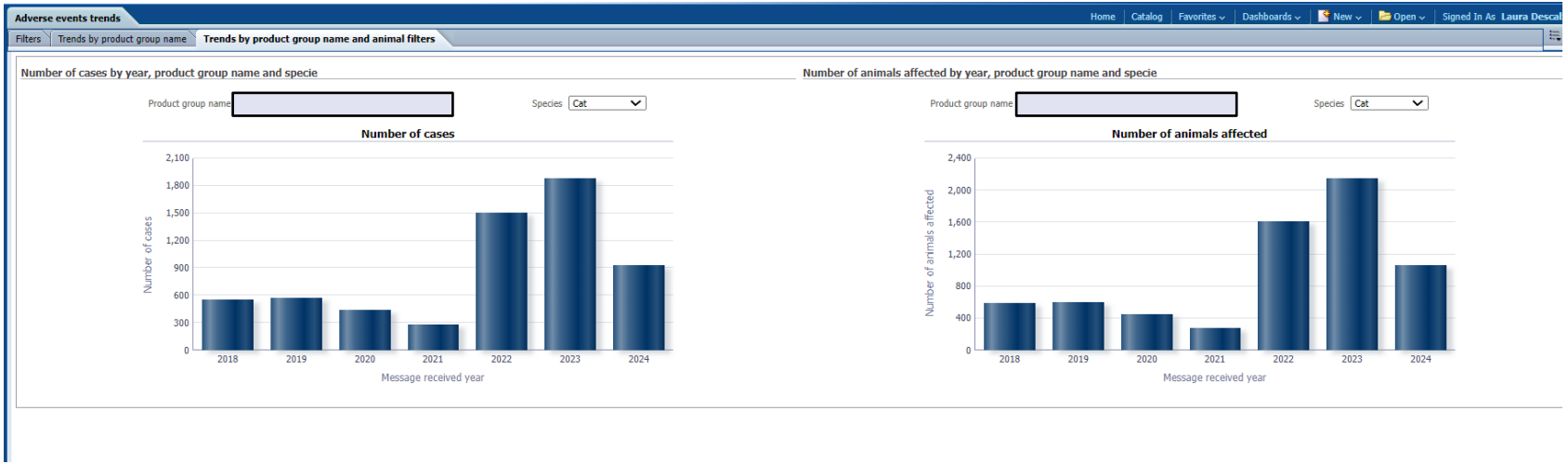
DWH: Adverse events trends dashboard

EUROPEAN MEDICINES AGENCY



DWH: Adverse events trends dashboard



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System Demo: let’s see it working!

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Value Streams

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Owner: Mireia Castillon/Ieva Lobaciute (ad interim)
Manager: Rob Hopping

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Owner: Steven Le Meur
Manager: Erik Gerritsen/Hugo De Jong

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Owner: Anne-Marie van Nederkassel
Manager: Melanie Loveday/Hannes Kulovits

Monitoring

Capabilities to monitor availability and safety of products

Owner: Pedro Pina Ferreira
Manager: Pedro Oliveira

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Owner: Leonidas Tertipis
Manager: Pedro Rodriguez/Christian Drescher

Product Lifecycle Management Insights - Newsletter

EUROPEAN MEDICINES AGENCY

Want to keep up to date on EMA's development of PLM VS products?

Scan the QR code and subscribe to the quarterly PLM Newsletter, titled:

Product Lifecycle Management Insights

Developments in EMA digital capabilities to manage the authorisation and lifecycle of medicines

Target Audience:

→ Pharmaceutical companies for Human and Veterinary products

Scope:

→ News on the latest digital capabilities and upcoming events for:

- Product Management Service (PMS) data
- Union Product Database (UPD)
- electronic Applications Forms (eAF)
- Electronic Product Information (ePI)
- Regulatory Procedure Management (RPM) for IRIS
- Substance, Product, Organisation, Referentials (SPOR) services

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PLM VS | Union Product Database (UPD)

Beyhan Mustafov, *Product Owner for UPD, EMA*

PI objectives & achievements Q2/2024

EUROPEAN MEDICINES AGENCY

Apr May June

PI OBJECTIVES

Implement spill-over from previous PI: Additional info at submission level (F187) & Enrich search criteria capabilities (F075)

Develop and implement in Q2 2024:

- New VNRA codes (C.10.d and C.10.e) to be added to the RMS Variation list (US 169611).
- Automatic sending of notifications by email (F051)
- Save and resume draft VNRA submissions by a MAH (F125).

Develop in Q2 2024 and implement in Q3 2024:

- API for Industry and external EU/MS organisations to product data (F037).
- Enrichment of the CSV file generated as a result of the Export functionality (F153).
- Enrich search by ATC vet code (US 151849 – *stretched scope*).

Analyse & Develop in Q2 2024 and implement in Q3 2024:

- Provision of QPPV email to the existing contact details of the QPPV (F182).

Analysis:

- UPD capability to group products following CMDv SPC harmonisation procedure (F127).
- API for MAHs regarding provision of availability status (F071 US2).
- Dedicated field "Precise Scope" in VNRA for Cas (F078).
- Download info related to the approval of a specific VNRA from a notification (F161).
- Bulk update of all products when an NCA has a new LOC ID (F207).
- Relationship between AvS and VoS (Task 151356).
- Analysis on how versions of an organisation need to be handled in UPD (F137-US1).
- Provide support to EMA's NFR team.
- Enrichment of the analytical capabilities to support the Data Quality Framework.

Strategic and Solution Architecture work in Q2 2024:

- Provide support to PMS team for the PMS go-live.
- Migration of all non-prod environments to single tenant.
- Move from Azure domain name to EMA owned domain name.
- Support PMS team with analysis for ESMP requirements for MBO and Pack Size (US 168691).
- Review of the OMS to UPD link (Analysis and design by using the Public OMS API).
- APIM Dev Portal has been deprecated and needs to be migrated to the new Portal versions.
- SIAMED delta migration from MDM DB (*Analysis and design Q2 2024, implementation Q3 2024*).
- Retrieve from UPD correct information on 2.5. Authorisation status (MA status) and 2.6. Date of authorisation status change for CAPs (US 162162).
- Support direct integration with PMS from DAP (Task 129896).
- Support for the integration of VoS and VNRA databases on the DAP (US 168221).

PI ACHIEVEMENTS

- ✓ **Implement spill-over from previous PI**: Additional info at submission level (F187) & Enrich search criteria capabilities (F075)
- ✓ **Develop and implement in Q2 2024:** New VNRA codes (C.10.d and C.10.e) added to the RMS Variation list (US 169611); Automatic sending of notifications by email (F051); Save and resume draft VNRA submissions by a MAH (F125).

Analysis:

- ✓ UPD capability to group products following CMDv SPC harmonisation procedure (F127).
- ✓ API for MAHs regarding provision of availability status (F071 US2).
- ✓ Dedicated field "Precise Scope" in VNRA for CAs (F078).
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- ✓ Enrichment of the CSV file generated as a result of the Export functionality (F153).
- ✓ Enrich search by ATC vet code (US 151849).

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Analysis:

- Bulk update of all products when an NCA has a new LOC ID (F207).
- Analysis on how versions of an organisation need to be handled in UPD (F137-US1).
- Enrichment of the analytical capabilities to support the Data Quality Framework.

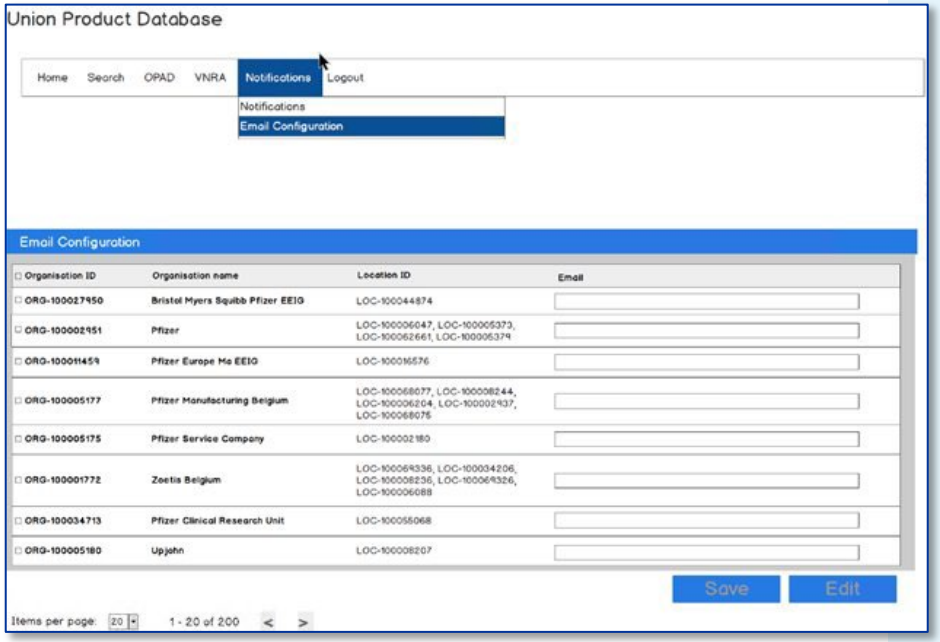
System Demo: let's see it working!

For MAHs: How to save and resume draft VNRA submissions (F125)

Automatic sending of notifications by email (F051)

EUROPEAN MEDICINES AGENCY

Configuration of **Email notifications**



Purpose: The aim of the notifications is to **inform Competent Authorities and MAH users** that specific actions have been performed in the UPD for which they should be aware, either for their information or to perform further actions.

How does it work: Super Users of each Organisation can set the receiving addresses via the "Email Configuration" form.

To Note: All emails will be sent from upd.notification@ema.europa.eu email address.
A **guide for Super Users** will be published on the EMA website shortly (w/c 1 July 2024)

Provision of QPPV email addresses in UPD

EUROPEAN MEDICINES AGENCY

Background

As per Regulation (EU) 2024/568 that will apply **from 1 January 2025:**

- NEW annual pharmacovigilance fee for non-CAPs will be charged.
- Similarly to the process used for the existing *human* annual pharmacovigilance fees, advice notes, chargeable units line listing(s)* and communications will be sent to the QPPV email address available in UPD.

What's new

Between August and September 2024 MAHs will be required to:

- **enrich the QPPV details** for their products in the UPD by providing the relevant email address for future use.
- This *ad hoc* feature will be available for a limited period of time only, with the exact dates to be communicated separately.

**The QPPV will receive chargeable units line listing for verification before the EMA issues the invoice for annual PhV fees for non-CAPs.*

For further information please consult the presentation and recording of the webinar held on 20/06/2024: New Fee Regulation: webinar for veterinary Marketing Authorisation Holders | European Medicines Agency (europa.eu)

Training sessions, recordings and available guidance materials

EUROPEAN MEDICINES AGENCY

Guides

- UPD Portal Guide to registration
- UPD Implementation Guide
- How CAs should update packages in UPD

Release notes

- Periodically published on EMA's UPD webpage

Q&A Docs

- UPD Q&As for Industry users
- UPD Q&As for Network users
- UPD Q&As about VoS

Webinars

- EMA's UPD webpage

Trainings

- Video tutorials (divided by all users, NCAs and MAHs)

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Product Lifecycle Management Insights - Newsletter

EUROPEAN MEDICINES AGENCY

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- Substance, Product, Organisation, Referentials (SPOR) services

slido # 9116064

PLM VS | Electronic Application form (eAF) / PLM Portal

***Kristiina Puusaari**, Product Owner for eAF, EMA*

Please note that Digital Application Dataset Integration (DADI) project has been phased out in favor of eAF and PLM Portal.

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PI objectives & achievements Q2/2024

EUROPEAN MEDICINES AGENCY

April | May | June

PI ACHIEVEMENTS – Q2 2024

- FHIR 5.0 in production ✓
- New home page design ✓
- System and environment stabilisation and performance improvements ✓
- Split/Match-Merge CAPs load in production – recommended use of web-based eAF for CAP variations ✓
- Performance improved list of applications ✓
- Form type auto selected ✓
- Package description column added ✓
- UX design to improve user experience ✓

PI PLANS Q3 2024

- **Performance improvements to expand the use for all EU procedures (i.e. non-CAP variations)**
- **Improvements of e.g. (small subset of planned stories)**
  - Features needed for non-CAP procedures
  - Proof of payment
  - Present and Proposed
  - Alternative ‘organization’ name
- **Previously developed features deployed into production:**
  - Add package (new pack size)
  - Name translations
  - Pending products (MRP/DCP national phase)

Q2 DEMO:

- New home page design
- Package description column
- Product updates in eAF following PMS go-live

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Human Variations electronic Application Form (eAF) – Key steps and milestones (June 2024)

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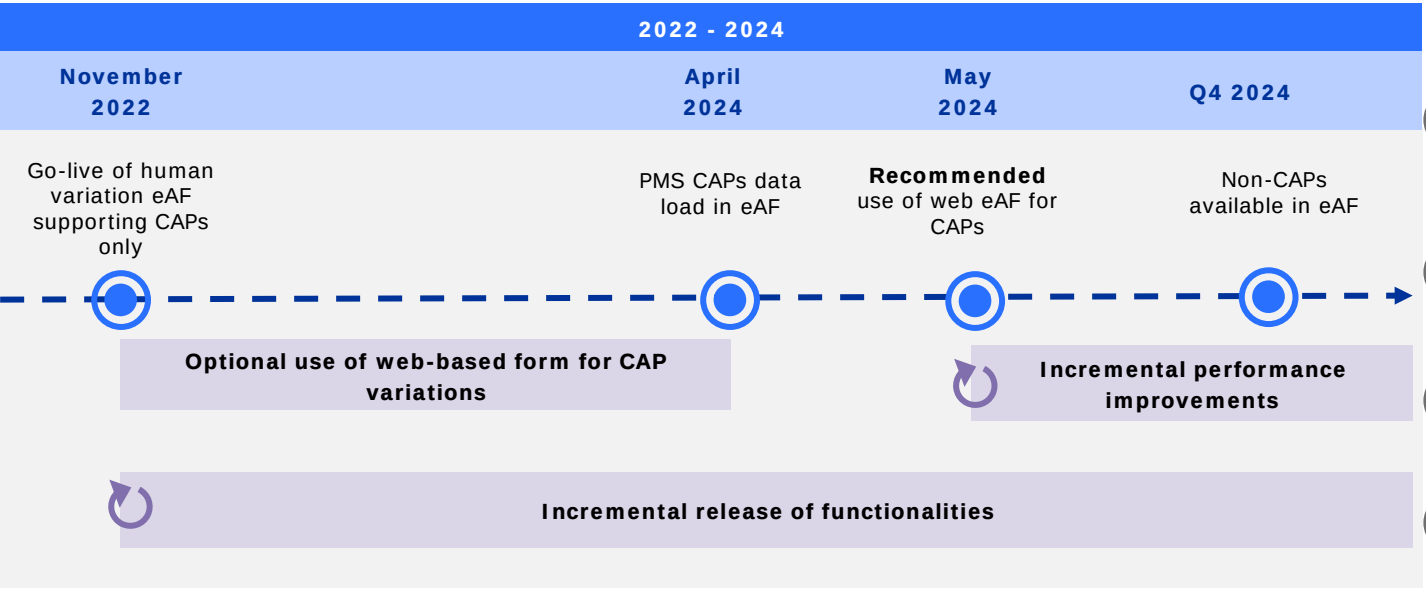


2025 & beyond	
UAT minus 2 months	UAT* announcement *(“Transition ready” form available)*
2 months after UAT	Confirmation of transition period start date
2 months after confirmation	Start of transition period
6 months after transition start	Use of variations web-form only

*including split & match-merge processes. The “Match-merge” process serves to include data from XEVMPD to products already released in PLM Portal. The “split” process serves to make released products ISO-IDMP compliant. Both processes are explained in detail in EU IG Chapter 7

*2nd external UAT to confirm functionalities required for mandatory use

Note: CAPs and NAPs data in PMS is sourced from EMA’s internal database and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key step/ Milestone

Dev activities for Human variations eAF

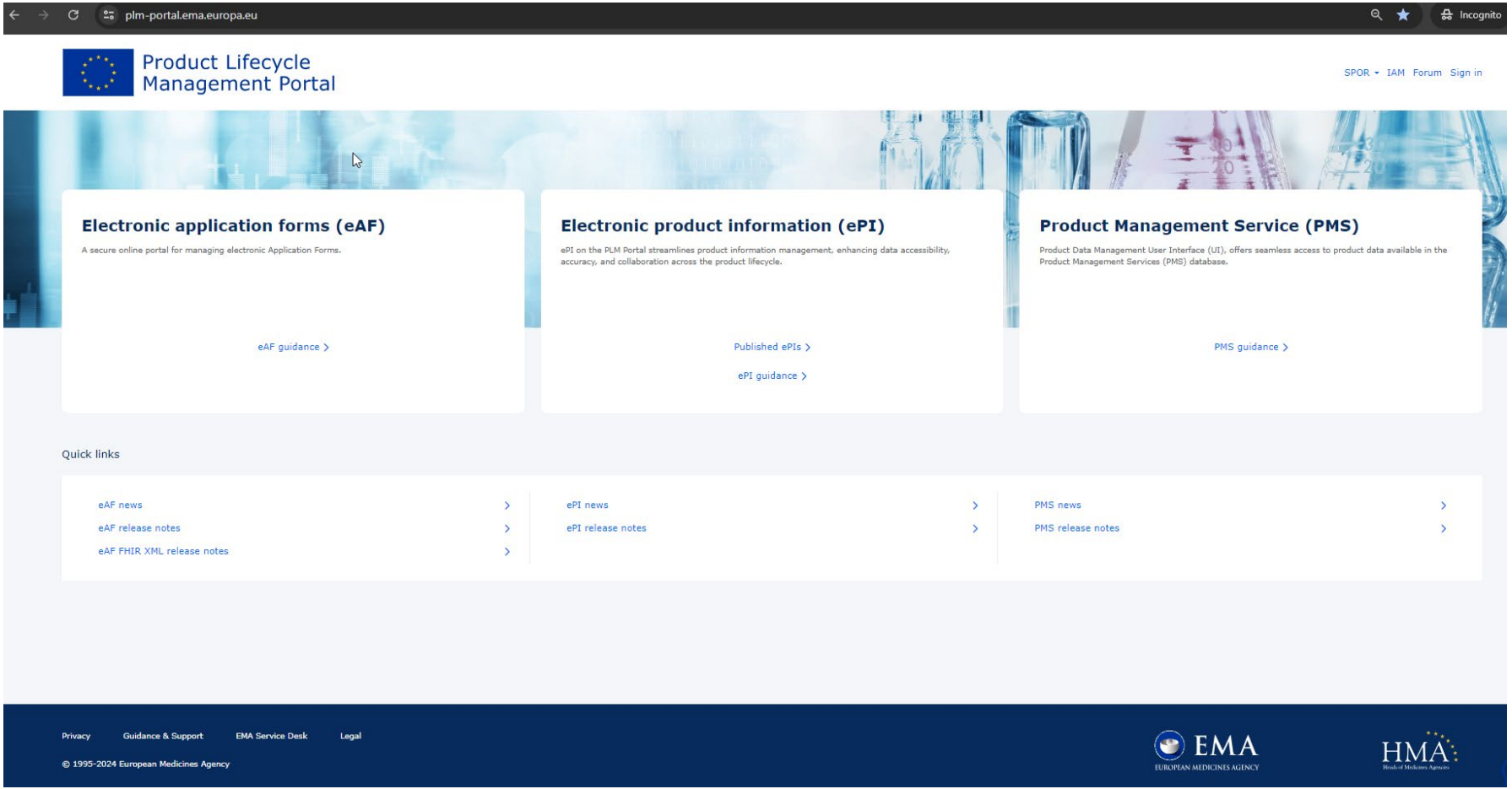
Recurring activity

Timeframes

System Demo: let's see it working!

New homepage – live since May

EUROPEAN MEDICINES AGENCY



New homepage – live since May

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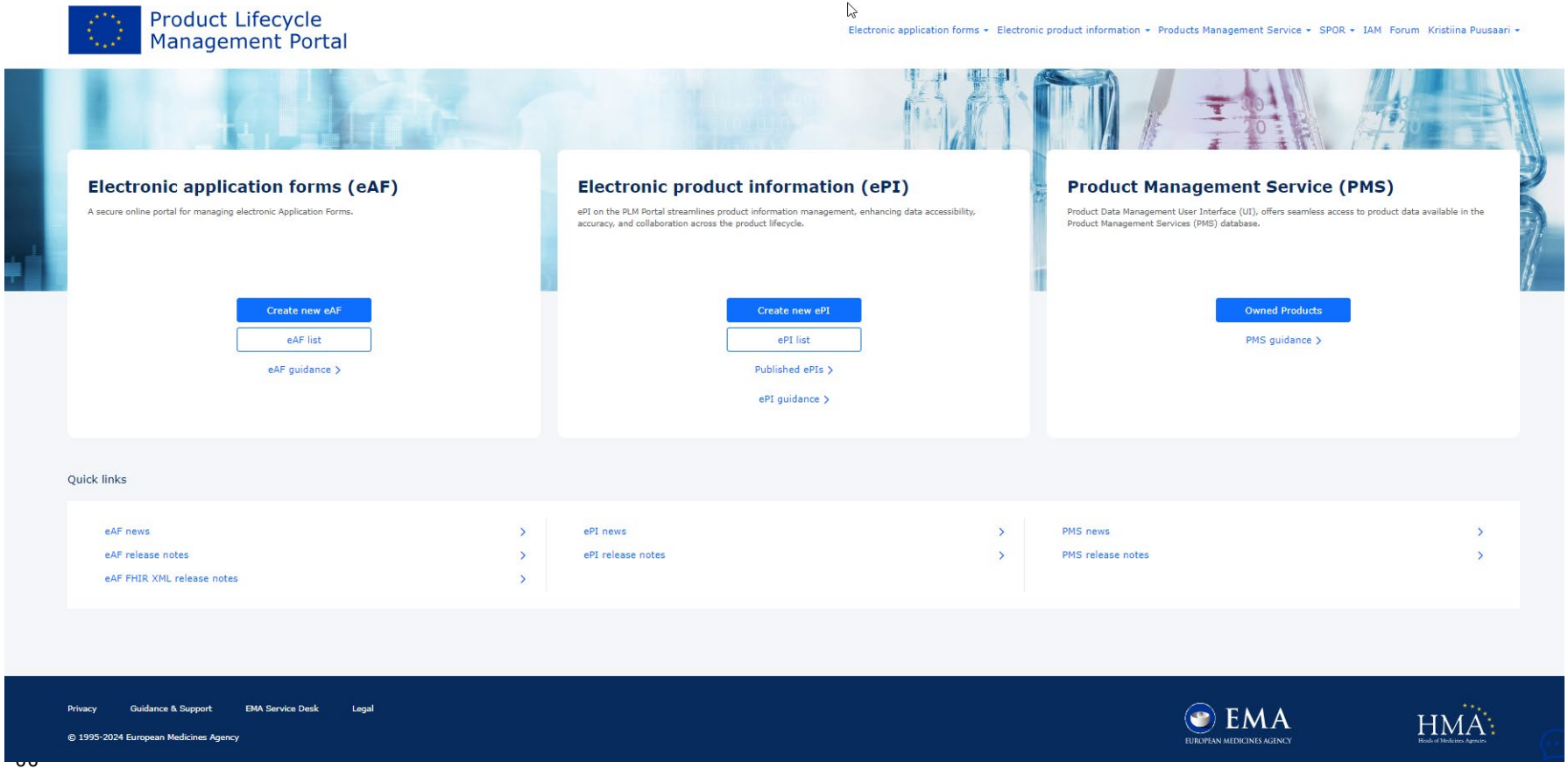
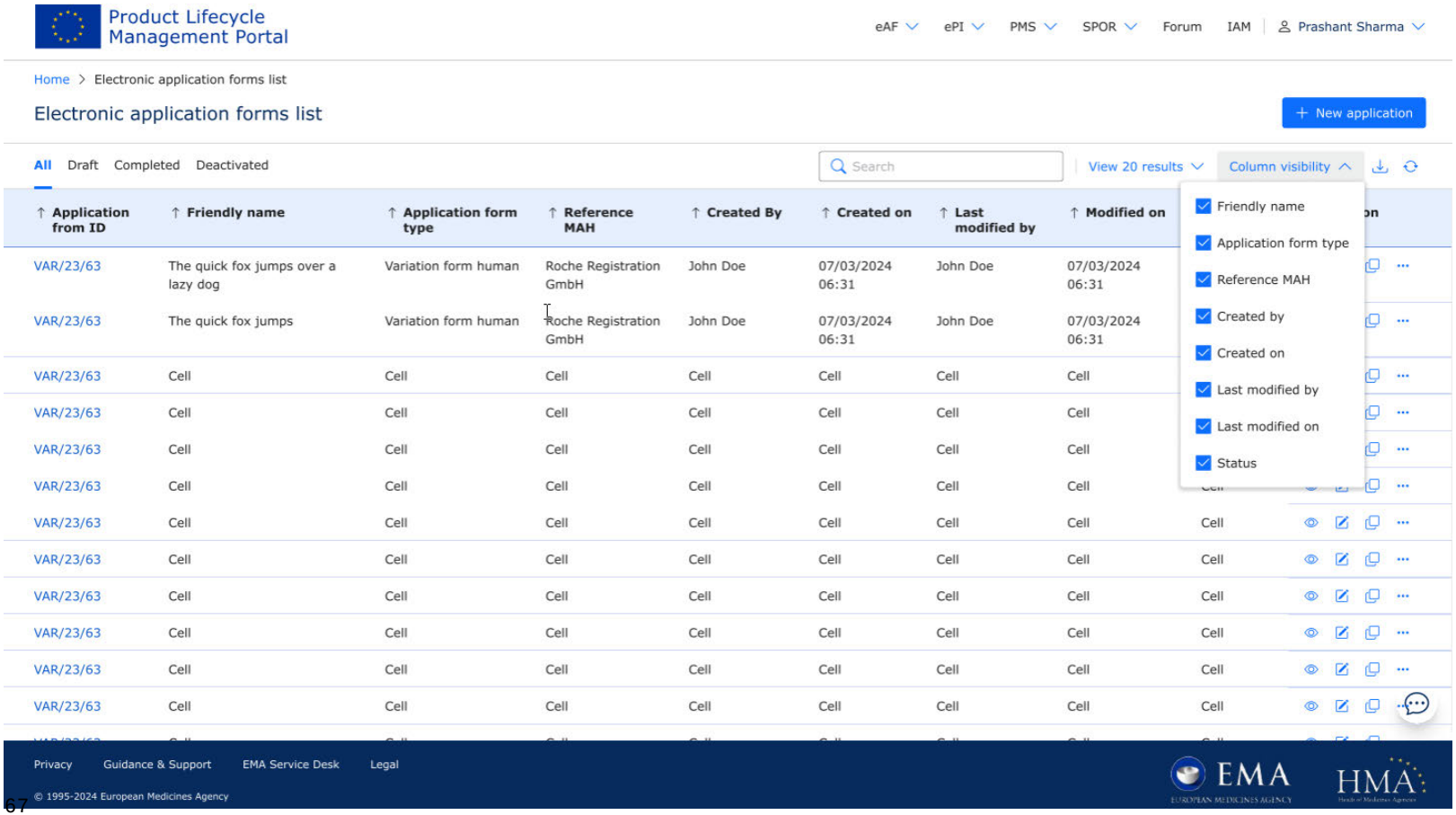
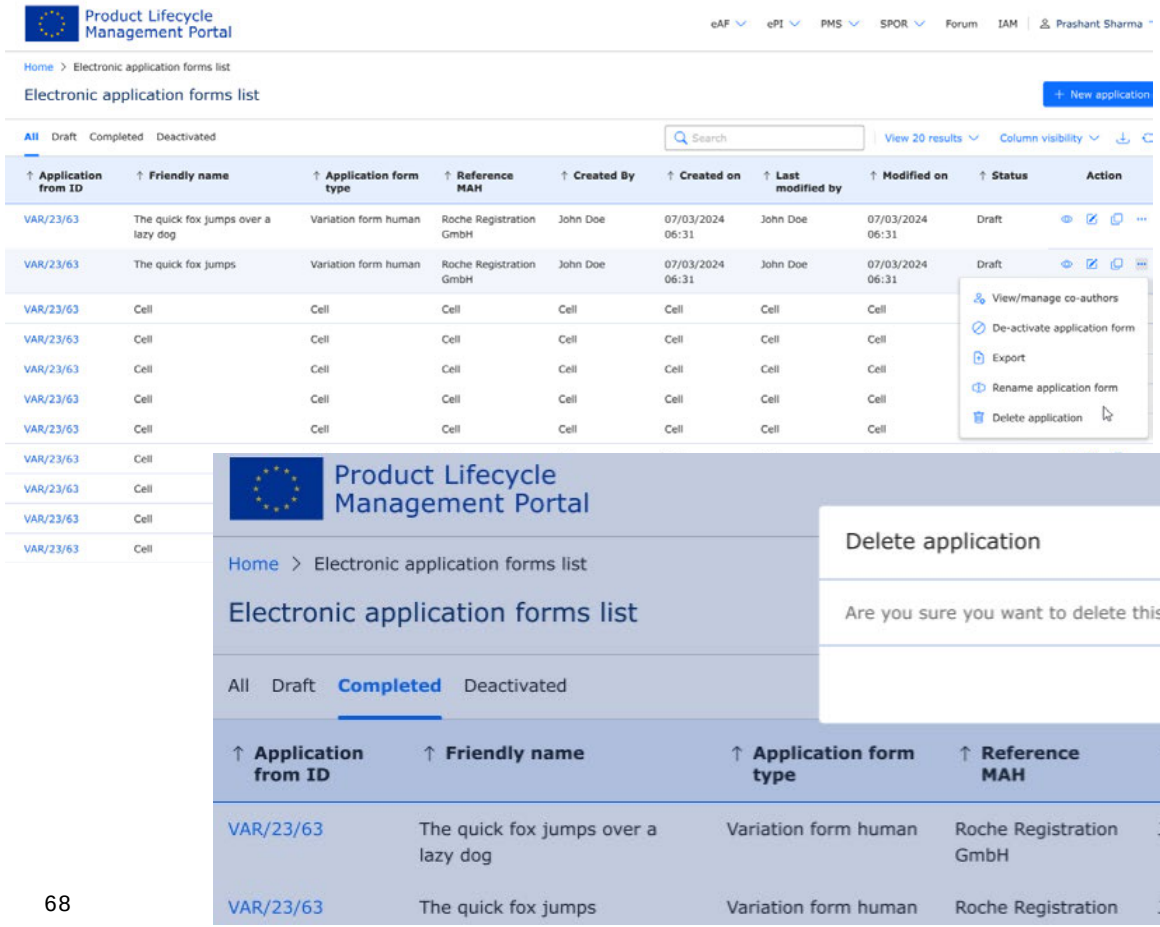


New UX designs – example of application list



New UX designs – example of application list

EUROPEAN MEDICINES AGENCY



New UX designs – example of create new application

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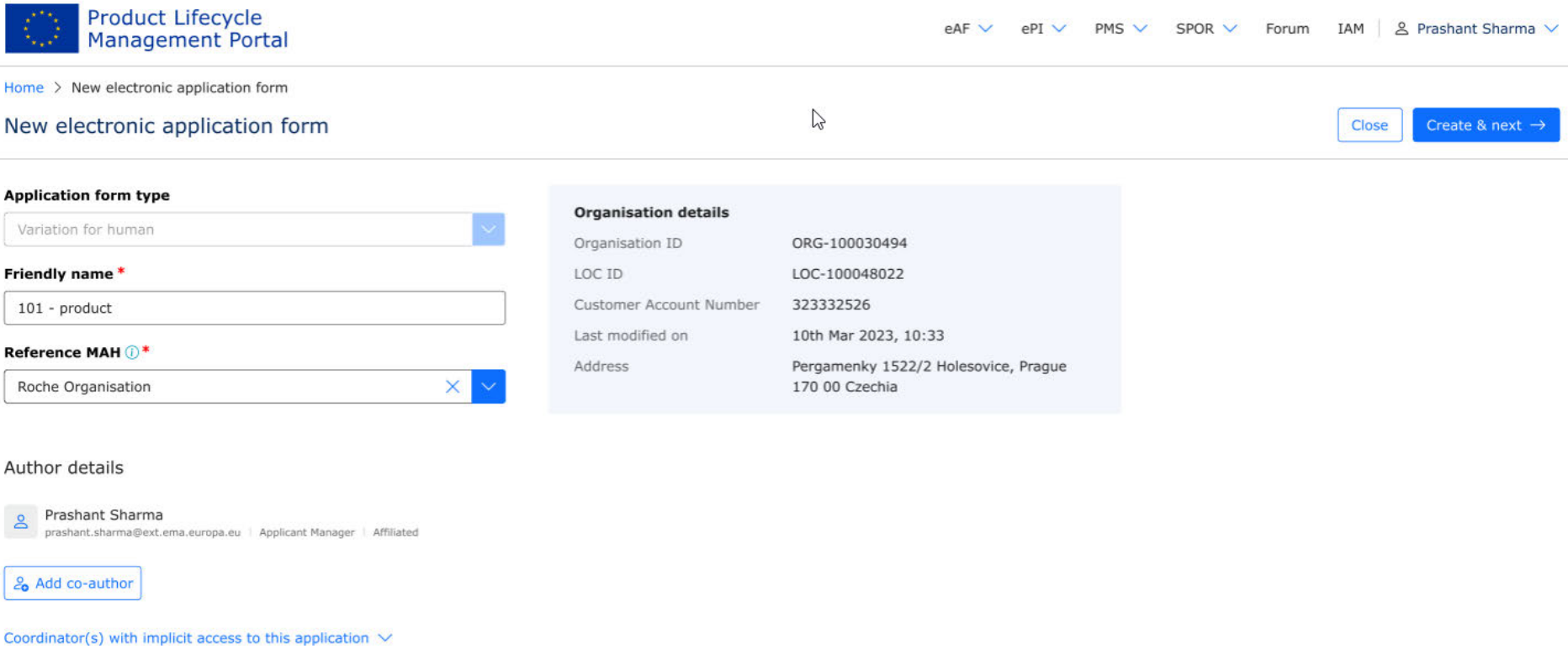
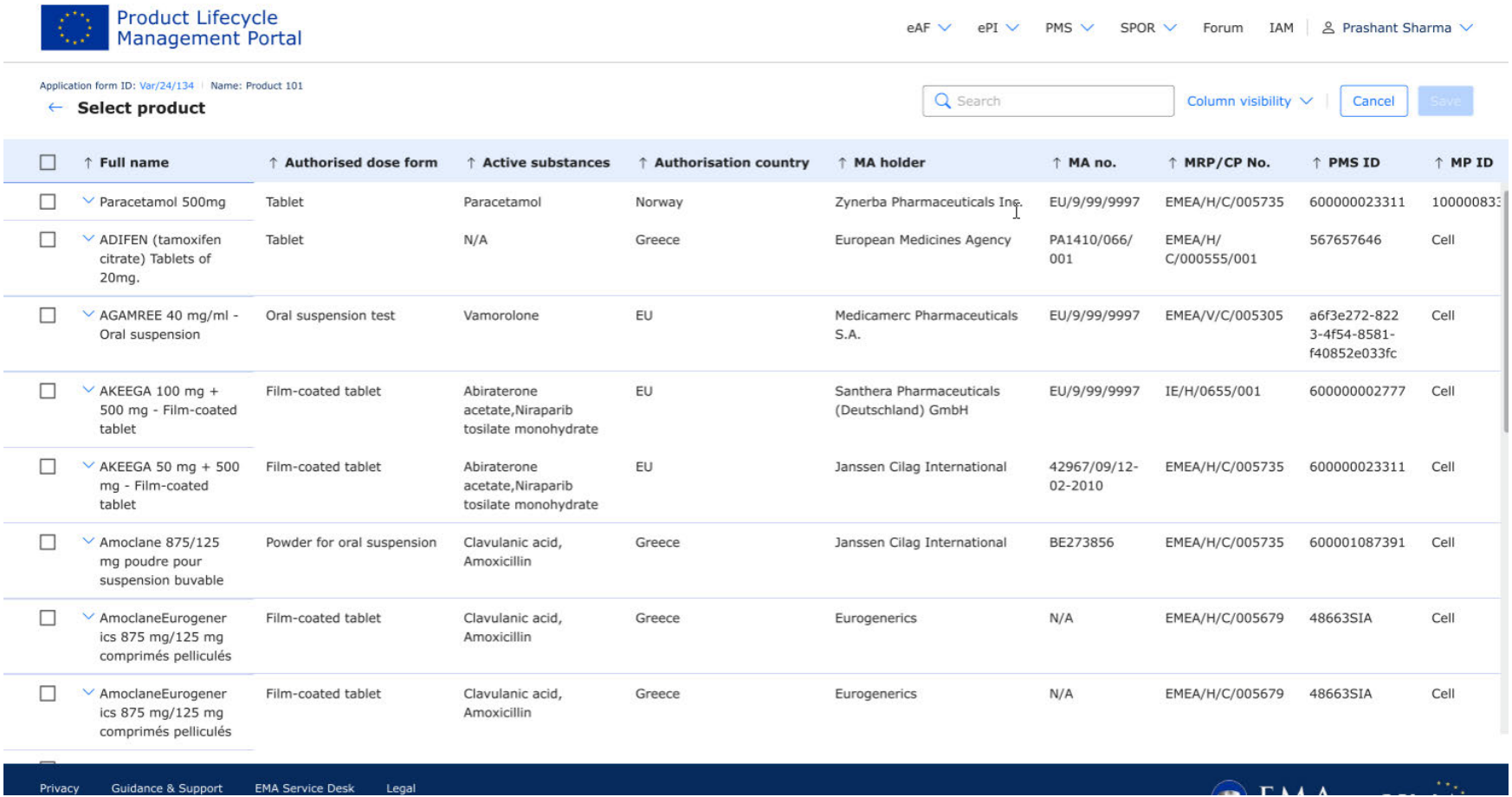
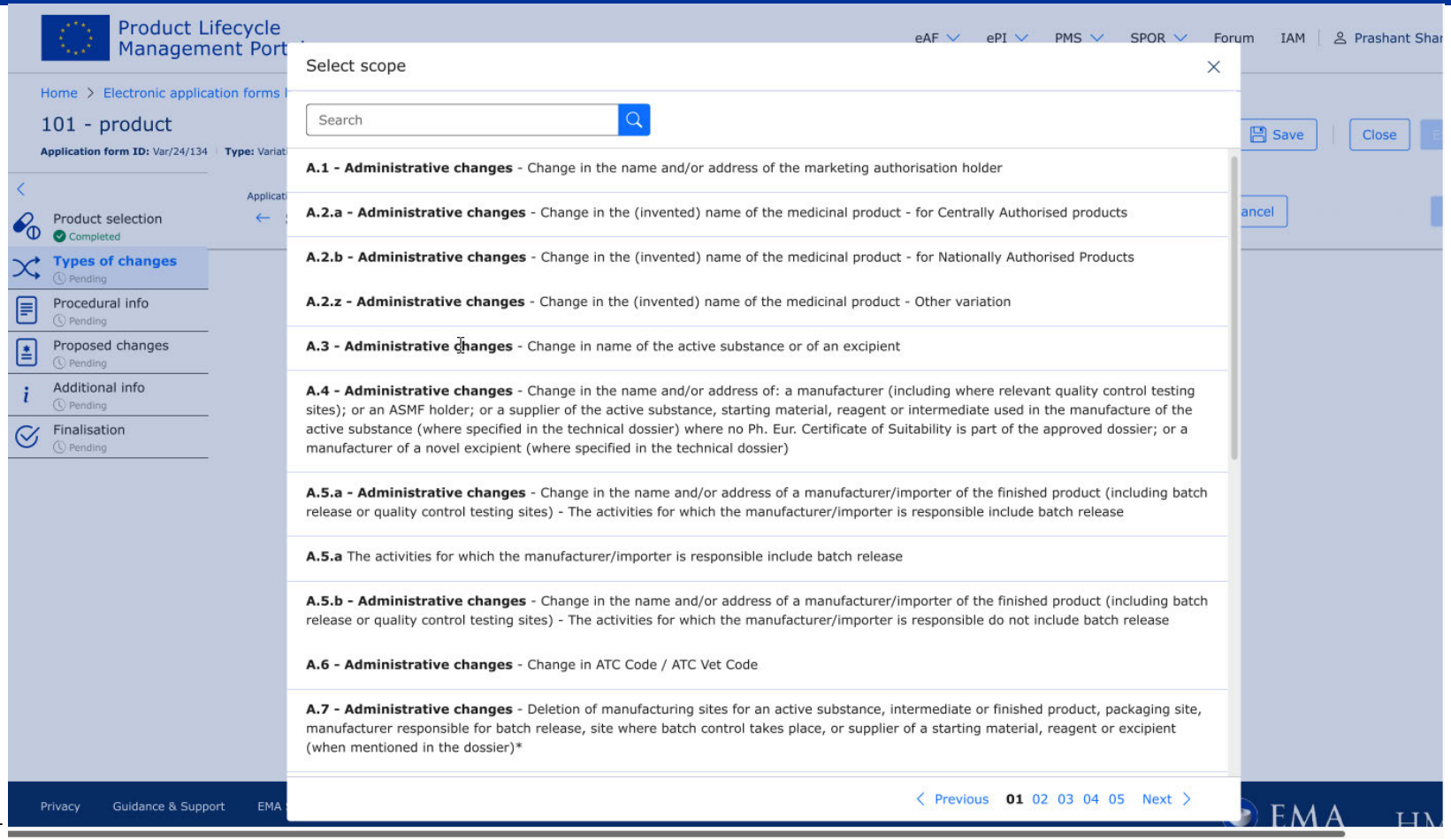


New UX designs – product selection

EUROPEAN MEDICINES AGENCY



New UX designs – Types of changes i.e. scope selection



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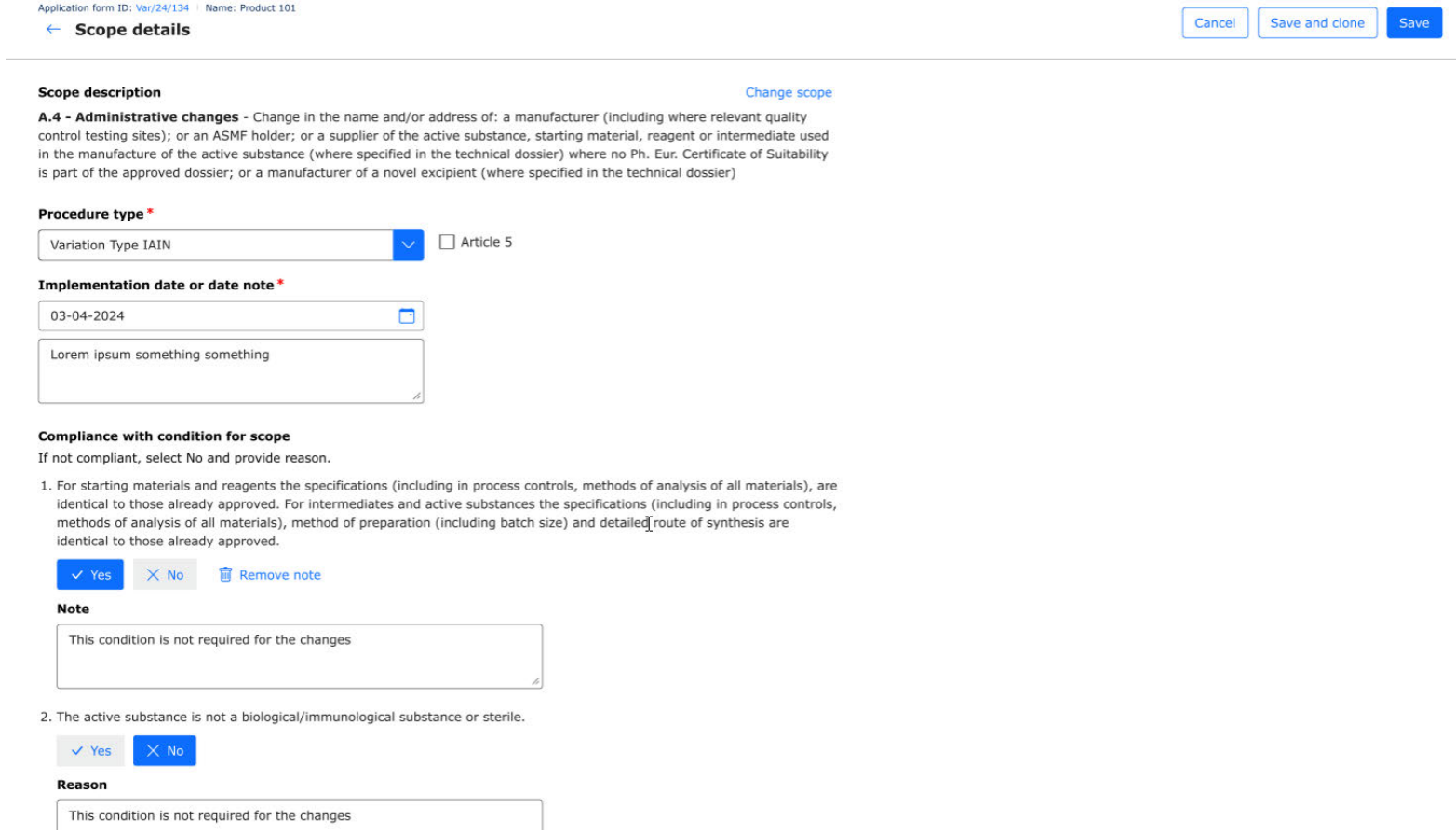

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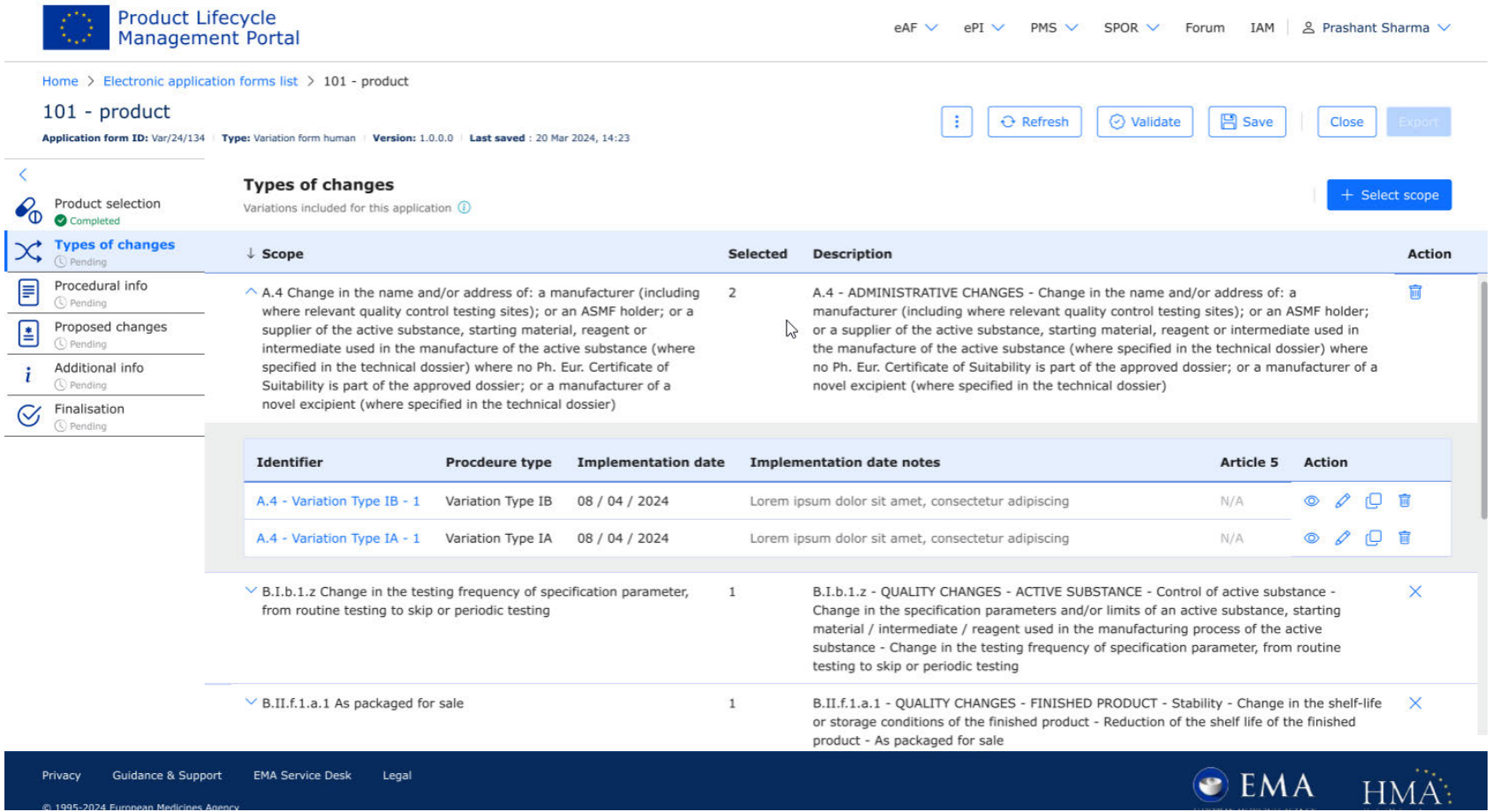
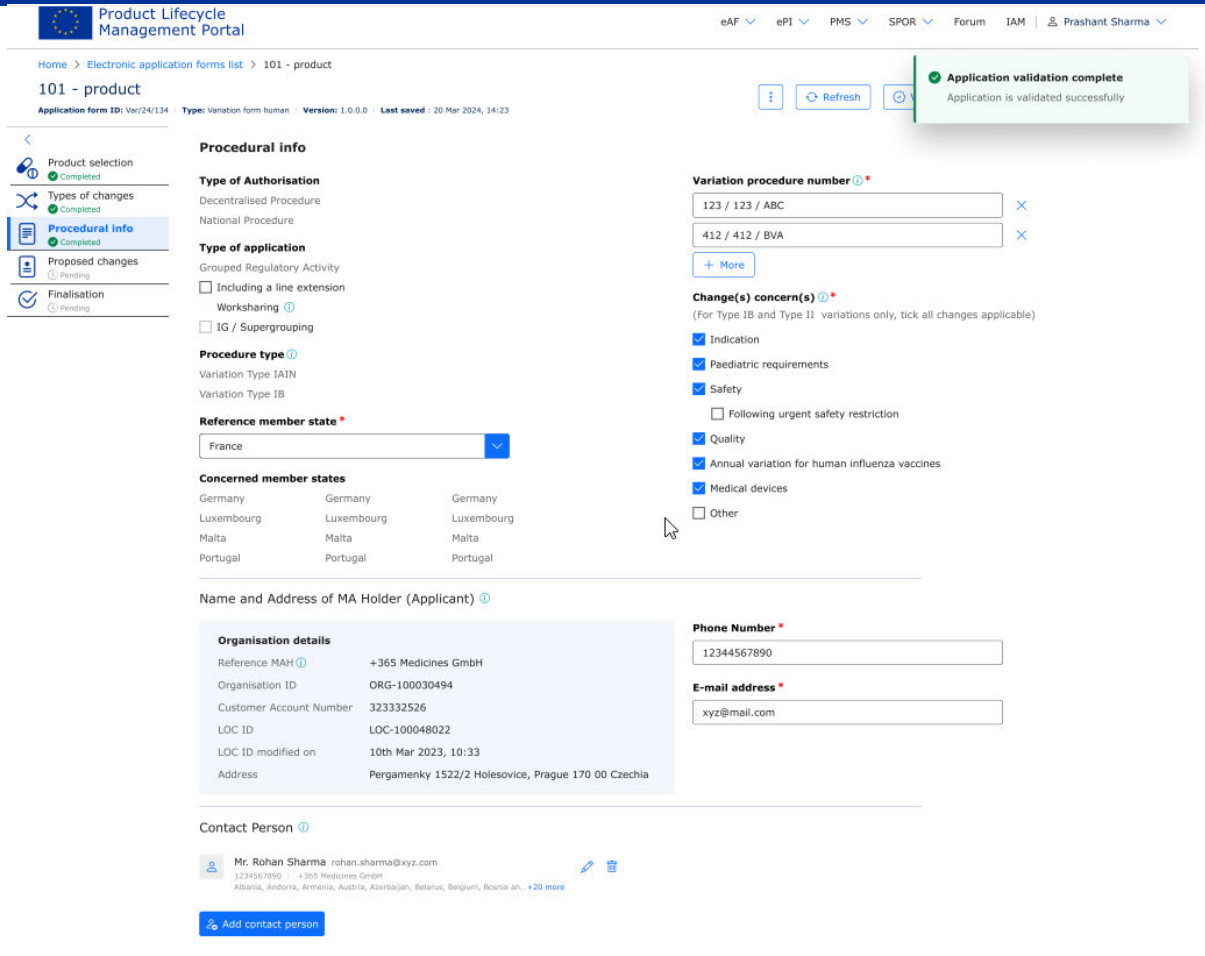


New UX designs – Procedural information

EUROPEAN MEDICINES AGENCY



New UX designs – Present and Proposed

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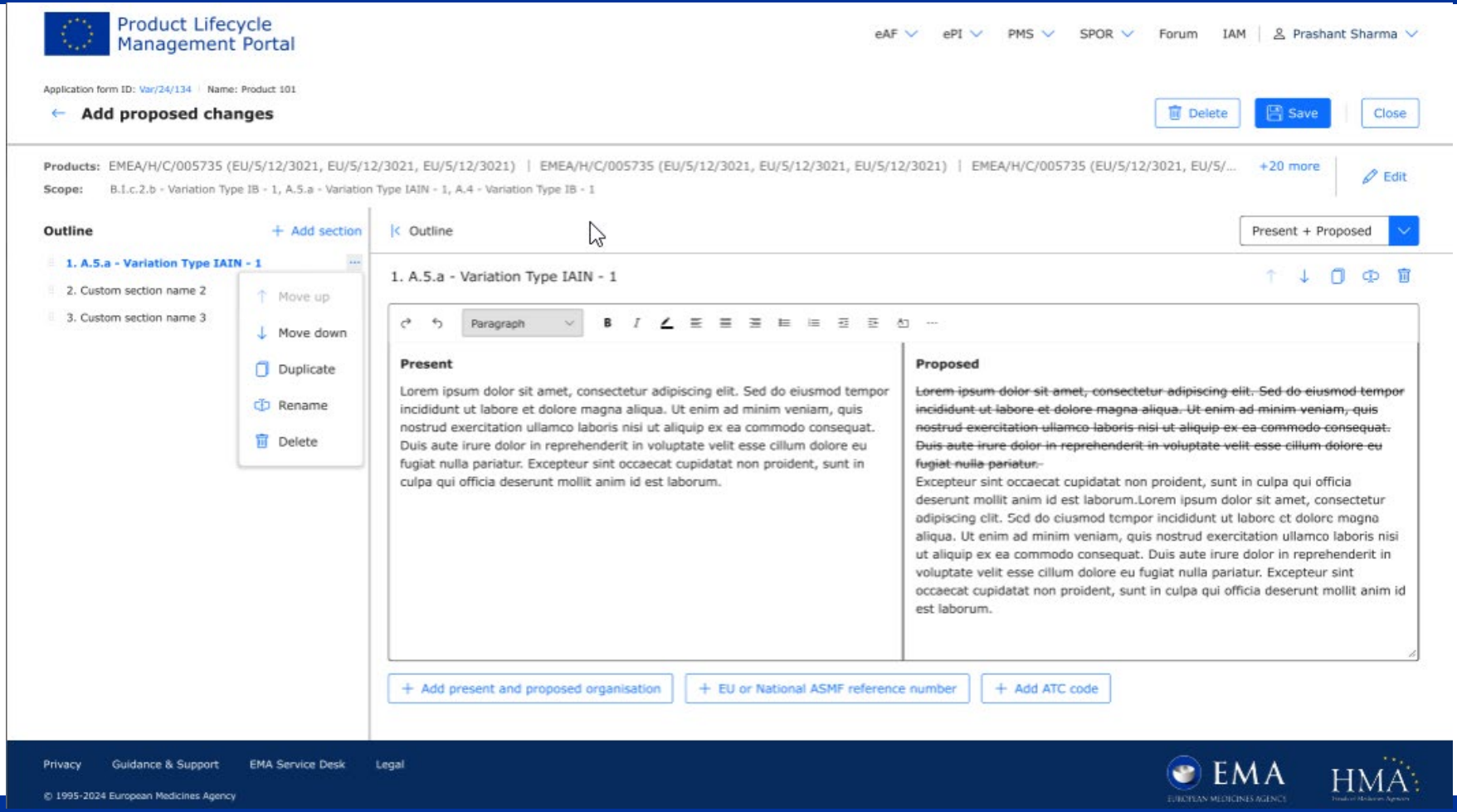

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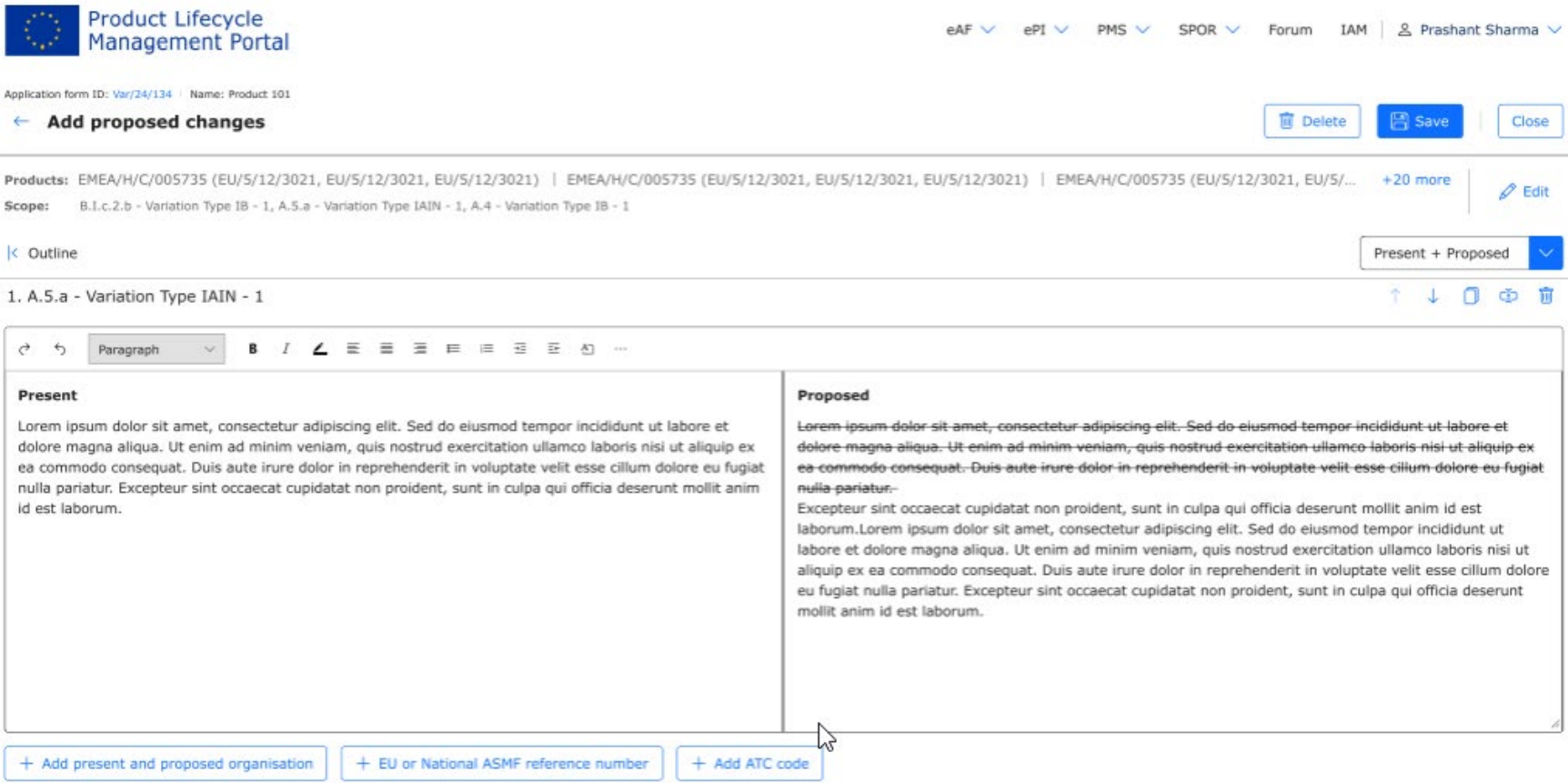

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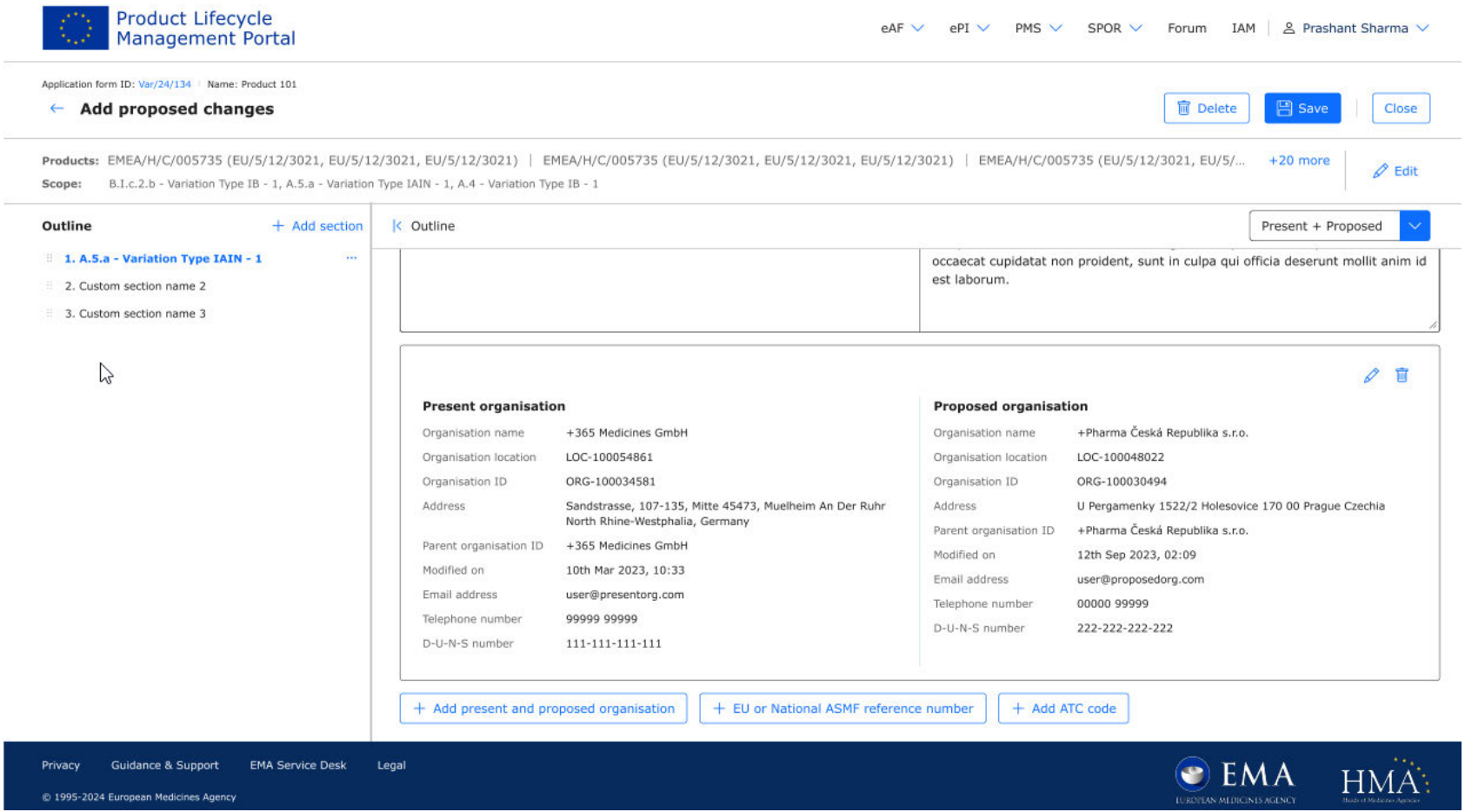
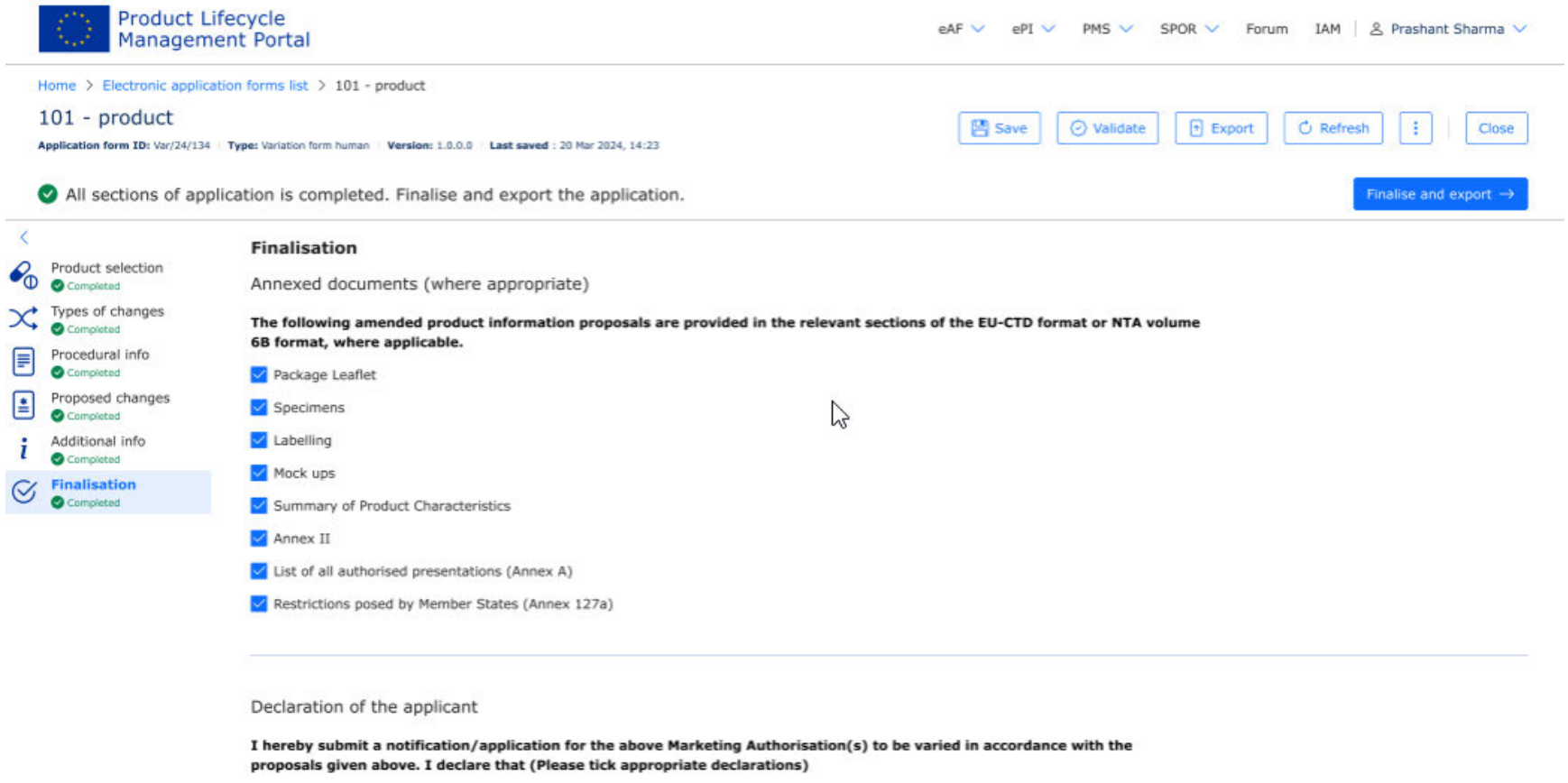


New UX designs – Finalisation

EUROPEAN MEDICINES AGENCY



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slido # 9116064

PLM VS |Product Management Service (PMS)

Marcos Fernandez Gomez, *Product Owner for PMS, EMA*

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PI Objectives Q3/2024

EUROPEAN MEDICINES AGENCY

Q2 2024 work

What we did:

- **XEVMPD data to PMS**
- PMS API Production Go-live (Read/Internal users)
- **Released PMS user roles in IAM Production**
- Solve any bug that is a stopper for PMS go-live
- RMS/XEVMPD data mapping support

- Released **new version of EU IG**:
  - EU IG Introduction
  - EU IG Chapter 1
  - EU IG Chapter 5 & Annex A
  - EUI IG Chapter 7
  - On-boarding of users to SPOR data services

Q3 2024 work

What we aim:

- **PMS API Production Go-Live (Read/External registered users)**
- Start discussions on Public PMS API
- Solve bugs on match and merge (CAPs that have not been matched with XEVMPD records)
- Start the development of **enrichment process** for manufacturers and structured data on pack sizes

- 11th July: **Pack Size Submissions: from XEVMPD to PMS** webinar

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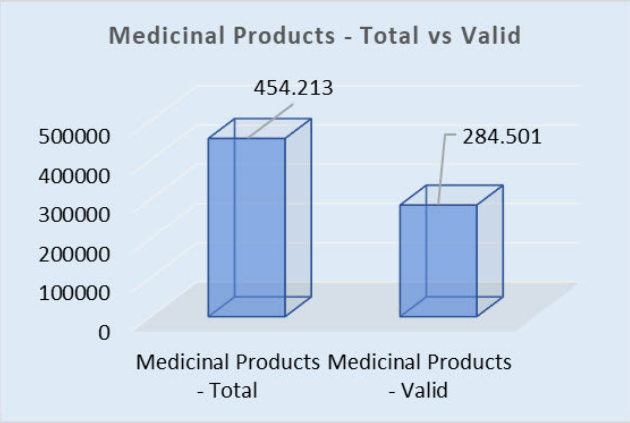
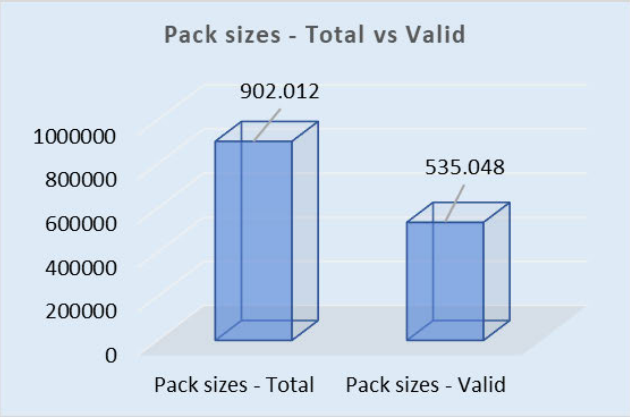
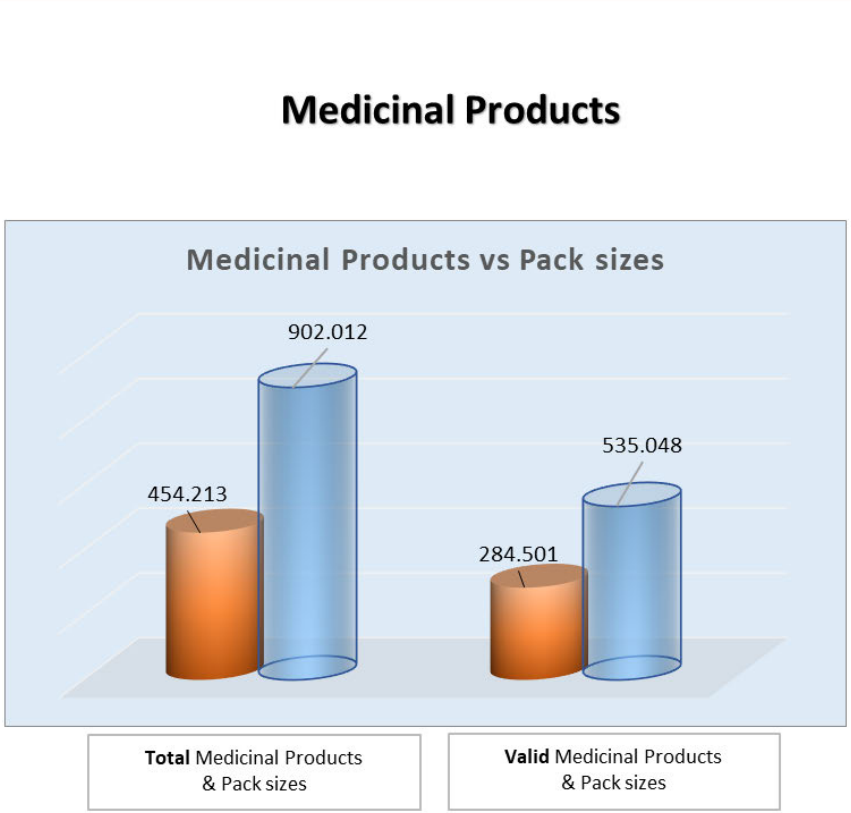
PMS migration in numbers

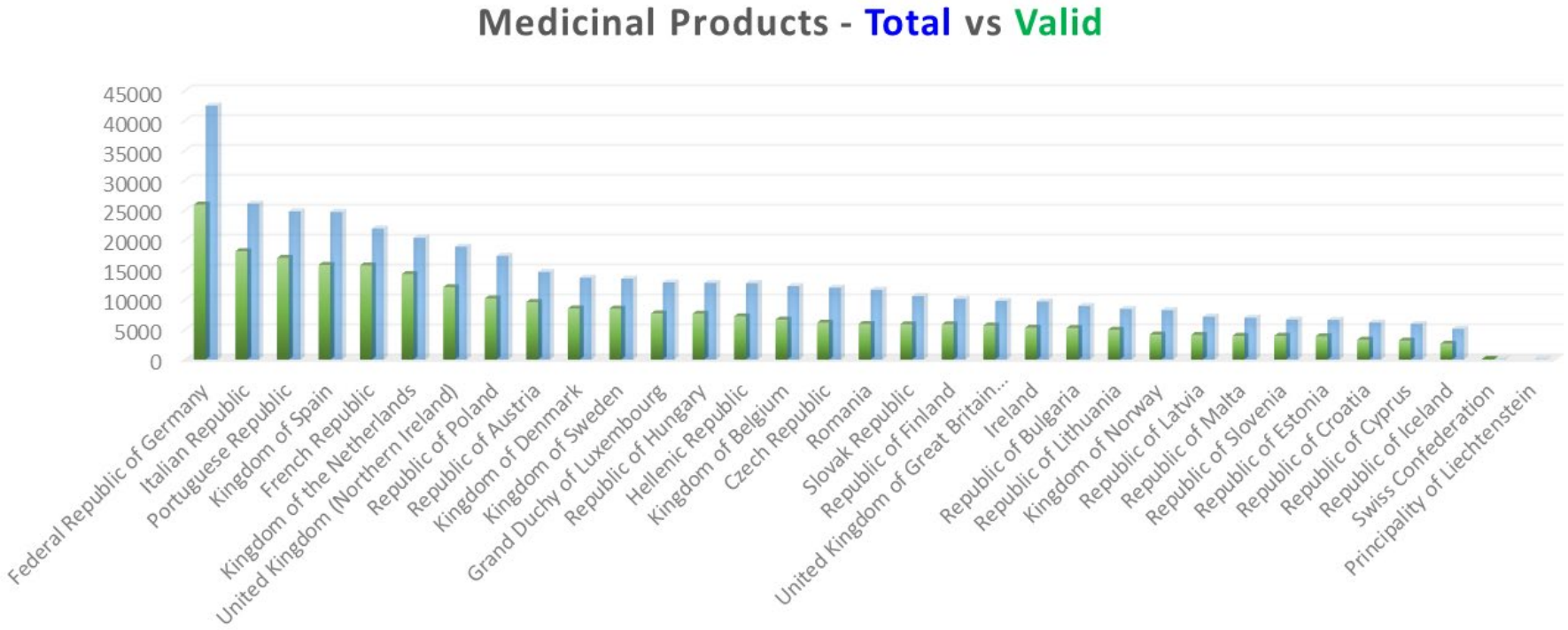






Valid = authorisation status is a valid one (valid, valid – transferred, valid – renewed, valid – suspended)

PMS migration in numbers



Valid = authorisation status is a valid one (valid, valid – transferred, valid – renewed, valid – suspended)

Next PMS training sessions

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PMS API Training

8 July 2024 (14:00 – 15:30 CEST)

→ Provide users with an explanation on how to request access to the PMS API for read only (Industry and NCAs)

Pack Size Submissions: from XEVMPD to PMS

11 July 2024 (10:00 – 11:30 CEST)

→ Provide users with an explanation on how to submit pack sizes to XEVMPD to support ESMP on the Union List of Critical Medicines

The events will take place on WebEx.

Details are published soon on EMA Website.

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PLM VS |Product User Interface (UI)

***Veronica Lipucci Di Paola**, Product Owner for PUI, EMA*

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PI Objectives Q2/2024

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Q2 2024 work

What we did:

- ***PMS PUI Go-Live*** *(31 May 2024)*
- Released PUI user roles in IAM Production
- Released view pages in PUI Production, Dynamic Reports & Public report
- Enabled export of data (BI reports, Excel, XML)
- Improvements on UI/UX
- Released PUI guidance and updated EU IG Chapters

Q3 2024 work

What we aim:

- ***Release non-CAP data in PMS PUI***
- Monitoring performance of PUI VIEW pages
- Progressing with Edit pages development
- Progressing on the design of Enrichment process
- Improve performance of PUI EDIT pages
- Extending the public report dataset

Demo

What we demo:

- PMS PUI pages: EV code(s), Document attachment, data fixes
- New ESMP dynamic report for data analytics
- Public PUI Human Medicines Report

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System Demo: let’s see it working!

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PLM VS | Electronic Product Information (ePI)

***Evinn Drusys**, Network Product Owner for ePI, AEMPS*

***Elizabeth Scanlan**, Product Owner for ePI, EMA*

ePI project supported by funding from the European Union EU4Health programme.

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ePI PI achievements Q2/2024 & objectives Q3/2024

EUROPEAN MEDICINES AGENCY

April | May | June | July | August | Sept

PI ACHIEVEMENTS – Q2 2024

- Ongoing support to pilot participants: all ES, NL, SE procedures now completed ✓
- FHIR IG and profiles published ✓
- UAT on portal functionality completed ✓
- FHIR upload functionality developed ✓
- Automated testing foundations ✓

PI OBJECTIVES – Q3 2024

- **Conclude ePI pilot** and recommend follow-up actions
- Consolidate **FHIR upload** functionality
- Extend **automated testing**
- Preparatory work on **QRD template versioning**

Q2 DEMO:

- Pilot update
- FHIR IG and profiles
- UAT results
- FHIR import

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ePI pilot progress

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AEMPS: Spanish Medicines and Healthcare Products Agency
DKMA: Danish Medicine Agency
MEB: Medicines Evaluation Board (Netherlands Medicines Agency)
MPA: Swedish Medical Product Agency

21 Total Number of **ePIs published** in the Pilot

1 **Ongoing procedures CAP**

1 **Ongoing procedures NAP / MRP / DCP**

2 **Not yet started NAP / MRP / DCP**

EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Published on	Medicines regulatory agency	Country of authorisation
	for nebulisation		NAP	Ingelheim AB	04:09 PM	Products Agency	Sweden
EPI/23/1033	Voltaren Emulgel 1.16 %, Gel		NAP	GlaxoSmithKline Consumer Healthcare B.V.	26/01/2024 10:04 AM	Medicines Evaluation Board	Netherlands
EPI/23/1025	Efavirenz Aurovitas 600 mg comprimidos recubiertos con película EFG	NL/H/2950/001/IB/024	MRP/DCP	Aurovitas Spain S.A.	18/01/2024 03:54 PM	The Spanish Agency Of Medicines And Medical Devices	Spain
EPI/23/1028	ZOLADEX TRIMESTRAL 10,8 mg IMPLANTE EN JERINGA PRECARGADA	NA	NAP	Astrazeneca Farmaceutica Spain S.A.	22/12/2023 02:23 PM	The Spanish Agency Of Medicines And Medical Devices	Spain
EPI/23/1009	Brukinsa	EMEA/H/C/004978/II/0014	CAP	BeiGene Ireland Limited	24/11/2023 03:29 PM	European Medicines Agency	European Union
EPI/23/1016	Fluticasonpropionaat Teva 50 microgram, neusspray 50 microgram/dosis	RVG 33656	NAP	Teva Nederland B.V.	24/11/2023 09:53 AM	Medicines Evaluation Board	Netherlands
EPI/23/1022	Imatinib Teva	EMEA/H/C/002585/N/0053	CAP	Teva B.V.	07/11/2023 10:15 AM	European Medicines Agency	European Union
							Swedish

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System Demo: let's see it working!

Q2 DEMO:

- FHIR IG and profiles

PLM portal — ePI User Acceptance Testing: Thank you to our motivated and conscientious testers!

Scope

- ePI registration process in IAM and ePI registration guide
- ePI creation, management, approval, publication and ePI user guides

Timelines

3 - 7 June 2024	10 – 21 June 2024	Ongoing
Role requests	**Testing**	***Triage***

No. Testers

100 Testers

50 Regulator testers	***21 NCAs:*** Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden
50 Industry testers	***6 Trade Organisations:*** Medicines for Europe, Vaccines Europe, AESGP, EFPIA, EUCOPE, EuropaBio

Findings

Access	• Users could find, apply for, approve ePI roles and log in to PLM • Access issues from some users to be investigated
Portal	• User-friendly navigation of portal • Time taken by publishing action • Enhancements to optimize UI
Guidance	• Guidance needed for PIs which differ from QRD template

System Demo: let's see it working!

Q2 DEMO:

- Import FHIR

Product Lifecycle Management Insights - Newsletter

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Regulatory Procedure Management (IRIS)

Madalina Duta-Mare, *product owner for RPM (PLM), EMA*

Sara Santos, *subject matter expert for RPM (PLM), EMA*

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Roadmap for 2024-2025

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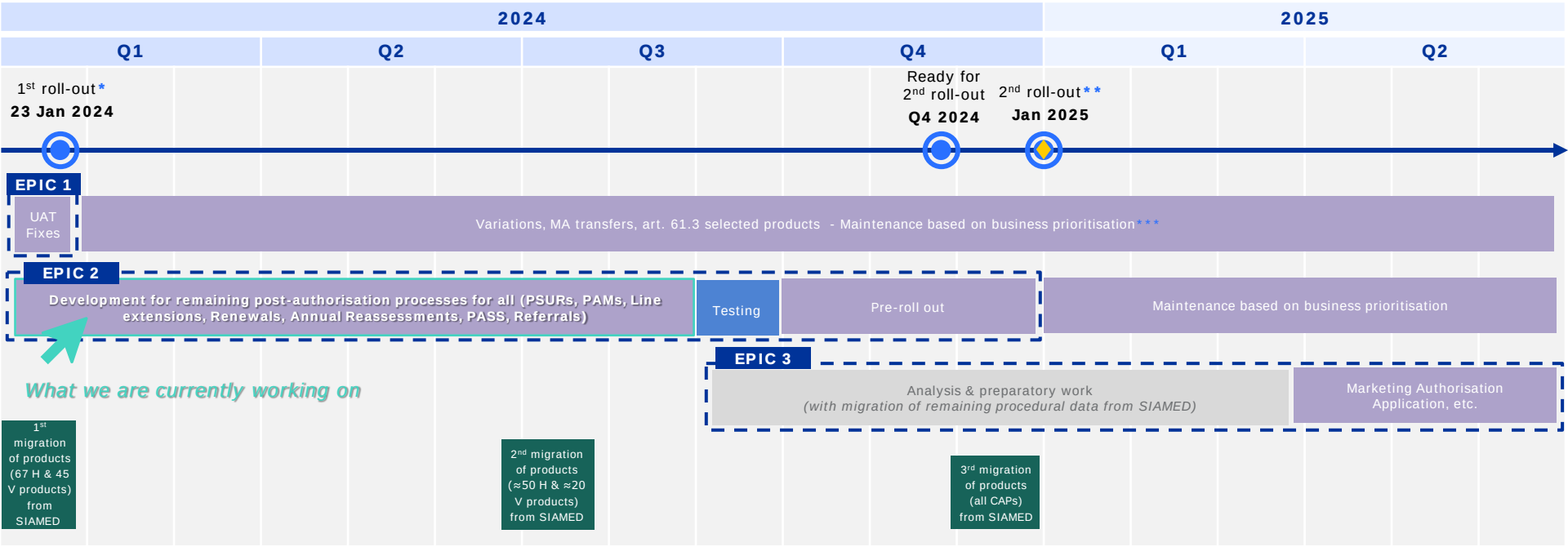

*for variations, MA transfers and Art 61.3 for subset of products (CAPs)

with Post-authorisation processes in IRIS for all CAPs (and involved NAPs) → **all EMA-led post-authorisation processes will be managed in IRIS in 2025

***Please note the ongoing development of RPM will happen epic by epic, with incremental improvements across the entire regulatory procedure management landscape.

Acronyms

AVS: Assisted Validation System
CAPs: Centrally Authorised Products
MA: Marketing Authorisation
NAPs: Nationally Authorised Products
PAMs: Post-Authorisation Measures
PASS: Post-Authorisation Safety Study
PSURs: Periodic Safety Update Reports
UAT: User Acceptance Testing

Legend

Milestone
Development activities
Migration activities
UAT activities
Analysis & preparatory activities
New Fee Regulation

What stays the same for impacted MAHs after 1st roll-out

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What stays the same

- **MAH's submission and responses to RSI via ECTD / VNeeS submissions**
- **Timelines** and **active email notifications** on the main milestones of the submission (e.g. start of the procedure, requests for Supplementary information (RsI), Outcomes etc.
- Requests for **withdrawal of single scopes** (via email)
- Receipt of **European Commission Decision** (via Eudralink)
- **Content** of the documentation
- **Guarantee of confidentiality**

Key changes for Industry users

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Case number use

Format: {agency ID}/{process group type (case form)}/{unique case number (10digits)}

Examples: Human: EMA/**VR**/0000076556

Veterinary: EMA/**VRA**/0000076559

While the current format contains detailed information within the procedure numbers, IRIS offers this **visibility through dashboards and views** within the system

EMA communication format

- **Emails sent from EMA** to the Industry portal contact contain **basic administrative information** on the submissions and the link to the IRIS industry portal *(no Eudralinks or attachment in the emails).*
- Emails from EMA IRIS will always come from EMA-IRIS@id.ema.europa.eu and contain a routing ID.
- During the procedure, the **document exchange** (outside eCTD/ VNeeS) takes place via **IRIS Industry portal**, relevant for **CAP** and **NAP MAHs** (in case of EMA led procedures, e.g. **PSUSA NAP**)

MAH Contact person

- The **MAH contact person for CAPs** - user stated in MAA eAF section 2.4.3 - for the product, by default becomes **portal contact and submission manager** in IRIS for the procedure

Lead product for Worksharing procedures

- For WorkSharing procedures in the Cover letter, the MAHs are requested to **indicate the "Lead product"** within the procedure in order to:
  - ✓ assign the correct Industry portal contact
  - ✓ set up a lead MAH for payment-related activities

Procedure withdrawal

- Procedure withdrawal (whole procedure) to be requested via **Industry Portal**

Communication with CAP MAHs for procedures

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EMA-led procedures managed in IRIS will include **CAPs**.

MAHs have the obligation to indicate a **product contact** for communication between EMA and the MAH (see Notifying EMA of changes to contact persons)

- The product contact person will be used for as default contact communication regarding the IRIS case.
- At their end, the contact person for the MAH will receive a notification and will be able to view the case data and collaborate with EMA for documents exchange.
- The contact can also add other users to view/collaborate and can change the contact person in the portal, for a specific case.

Communication with non-CAP MAHs for procedures containing NAPs

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EMA-led procedures managed in IRIS will include **Nationally Authorised Products (NAP/MRP/DCP) for PSUR, PASS and Referrals**.

MAHs will be requested to **indicate a contact person** for those procedures:

- The contact person will be used for communication regarding the IRIS case.
- At their end, the contact person for the MAH will receive a notification and will be able to view the case data and collaborate with EMA for documents exchange.
- The contact can also add other users to view/collaborate and can change the contact person in the portal, for a specific case.

Action required for Industry by the end of 2024

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1 *MAHs to be registered in OMS*

2 *MAHs products contact person for post-authorisation procedures has EMA account* ***(CAP and NAP MAHs)***

How to request access? Via the EMA Account Management System for all affiliated roles.

Instructions are available in the IRIS guide to registration and RPIs. *It is crucial that all new submissions in IRIS created from CRM for PLM procedures reaches the correct portal contacts.*

3 *Update product contact information*

Generic mailboxes are not supported for contact points:

MAHs to submit an **updated form** to **change all product contacts to personal emails**.

→ Instructions to submit the form **here**

PI objectives & achievements Q1/2024

EUROPEAN MEDICINES AGENCY

Jan | Feb | March

PI OBJECTIVES – Q2 2024

- Adjustments required for new processes to business requirements (I)
- Implement templates for Renewals, PSUR, PAM
- Implement timetables for remaining post-authorization procedures
- Implement fees for PSUR
- Plan change management activities for EPIC 2 go-live

PI ACHIEVEMENTS – Q2 2024

- Adjustments required for new processes to business requirements (I)
- Implement templates for Renewals, PSUR, PAM
- Implement timetables for remaining post-authorization procedures
- Implement fees for PSUR
- Plan change management activities for EPIC 2 go-live

DEMO:

- Post-authorisation procedures in IRIS
- For further detailed PSURs demo, please check the 13 June Industry Update Webinar recording (event web page)

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System Demo: let’s see it working!

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Value Streams

EUROPEAN MEDICINES AGENCY

Managing the Agency

Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration

Owner: Mireia Castillon / Ieva Lobaciute (ad interim)

Manager: Rob Hopping

Research and Development

Capabilities to support the development of new medicines and generation of scientific evidence

Owner: Steven Le Meur

Manager: Hugo de Jong / Erik Gerritsen

Product Lifecycle Management

Capabilities to manage the authorisation and lifecycle of medicinal products and certain medical devices

Owner: Anne-Marie van Nederkassel

Manager: Melanie Loveday/Hannes Kulovits

Monitoring

Capabilities to monitor availability and safety of products

Owner: Pedro Pina Ferreira

Manager: Pedro Oliveira

Technology Lifecycle Management and Information Security

Capabilities to manage information technology and security

Owner: Leonidas Tertipis

Manager: Pedro Rodriguez/Christian Drescher

Managing the agency VS | Experts Management Tool

Michael Vogl, *Product Owner for EMT, EMA*

System Demo: let’s see it working!

Closing

***Jean-Michel Becar**, Head of Portfolio Management Office, EMA*

Next System Demo:
18 September 2024