EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# 4. Update on the implementation of New Fee Regulation (EU) 2024/568

25 March 2024
Industry Standing Group (ISG)

*Jean Michel Mastio, Head of Finance Department*
*Claudia Galeazzo, Head of Procedures, Revenue and Expenditure*

# Goal of the meeting & Contents

EUROPEAN MEDICINES AGENCY

**Provide an overview of:**

- **The new fee regulation**
- **EMA's response to the change and the NFR solution development, including engagement with Industry**

1

**Introduction & background to the new fee regulation**
*Jean Michel Mastio, Head of Finance Department*

2

**EMA's response to the change and the NFR solution development, including engagement with Industry**
*Claudia Galeazzo, Head of Procedures, Revenue and Expenditure*

3

**Q&A**

# Introduction & background to the new fee regulation

*Jean Michel Mastio, Head of Finance Department*

# Regulation review cycle background

EUROPEAN MEDICINES AGENCY

EU Regulations usually have a **10-year review cycle**.

The review of the general EMA fee system was due in 2010 but **had to be re-prioritised due to the revision of the EU pharmacovigilance legislation,** which triggered a targeted **new legal proposal for PhV fees**.

**Since 2015,** the European Commission has been working on **the review of the EMA fee system**, in consultation with EMA (including a "Data Gathering" exercise) and NCAs.

In **December 2022, EC published its proposal for a revised EMA Fee Regulation.** This proposal was reviewed the European Parliament and European Council through the ordinary legislative procedure.

EP and Council agreed on the revised EMA Fee Regulation in Sept 2023. Final adoption and formal publication on 7 February 2024 - Regulation (EU) 2024/568 with **implementation date 1st January 2025**.

# Drivers for a new fee regulation and new state from 1st Jan 2025

EUROPEAN MEDICINES AGENCY

**Currently, fees charged by EMA are laid down in two regulations:**

- Council Regulation (EC) No 297/95 on the general fees for the Agency (CAPs only, human and veterinary medicines)
- Regulation (EU) No 658/2014 for pharmacovigilance activities (CAPs+NAPs, human only)

**Need for harmonisation and updates**

**Future state**

The remuneration: **single Union remuneration amount per relevant type of fee**.

The fees payable to the Agency

- will **be proportionate to the work** carried out
- will **be based on the workload and actual costs** for the services delivered by EMA and NCA (Network remuneration based on hours recorded and roles of rapporteur / co-rapporteur)

The fees paid to the Agency **will reflect the complex evaluations** and **recognise the contributions from Member States**' competent authorities necessary to obtain and maintain a Union authorisation.

# EMA’s response to the change and the NFR solution development, including engagement with Industry

*Claudia Galeazzo, Head of Procedures, Revenue and Expenditure*

# High-level changes for Industry

EUROPEAN MEDICINES AGENCY

- **The simplification** of the fee calculation (H+V)
- **The update of fee structures** now calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA (H+V)
- **The introduction of administrative fees** for withdrawals during validation and for incorrect incentives entitlement declaration (H+V)
- **The revision of payment methods and terms** for high-volume applications *(e.g., Scientific Advice, Certificates and Parallel Distribution)* (H+V)
- **The removal of certain fees** *(e.g., for Type I variations and renewals)* (H+V)
- **The introduction of new fees** *(e.g., for Pre-Submission, Referrals and re-examination of MA applications)* (H+V)
- **The introduction of a Pharmacovigilance annual fee** for Veterinary Nationally Authorised Products (V)
- **The revision of the methodology to apply incentives** for Veterinary Medicinal Products' procedures (V)

# Updates to available regulatory guidance



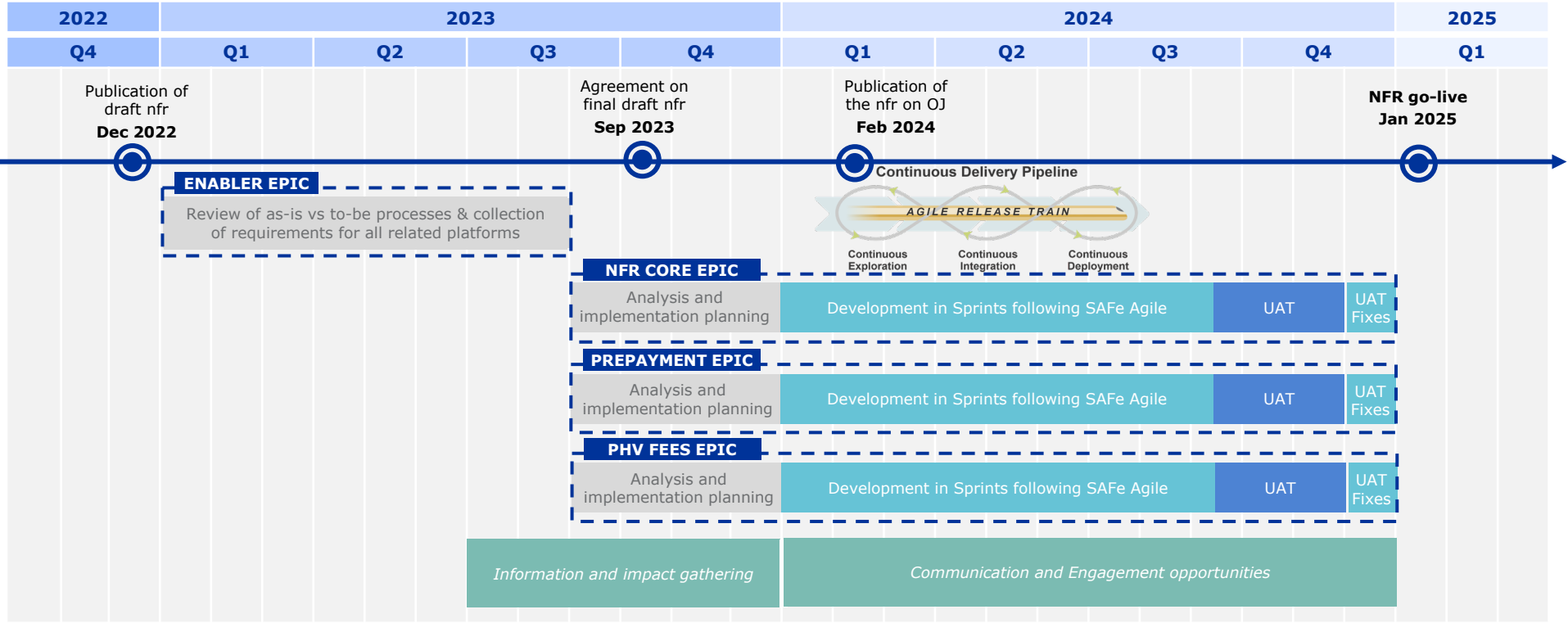
## Regulatory documents will be updated and made available on EMA's website

EMA's **regulatory documents**, user guides, web pages and FAQ documents are scheduled to be updated based on the new fee regulation **over the course of this year**.

*To ensure ample time to prepare for implementation of updated procedures and processes as explained in the documentation, the publication of these materials is planned for **Q4 2024.***

# Timeline for IT process payment preparation for implementation

EUROPEAN MEDICINES AGENCY




**Acronyms**

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

**Legend**

Milestone

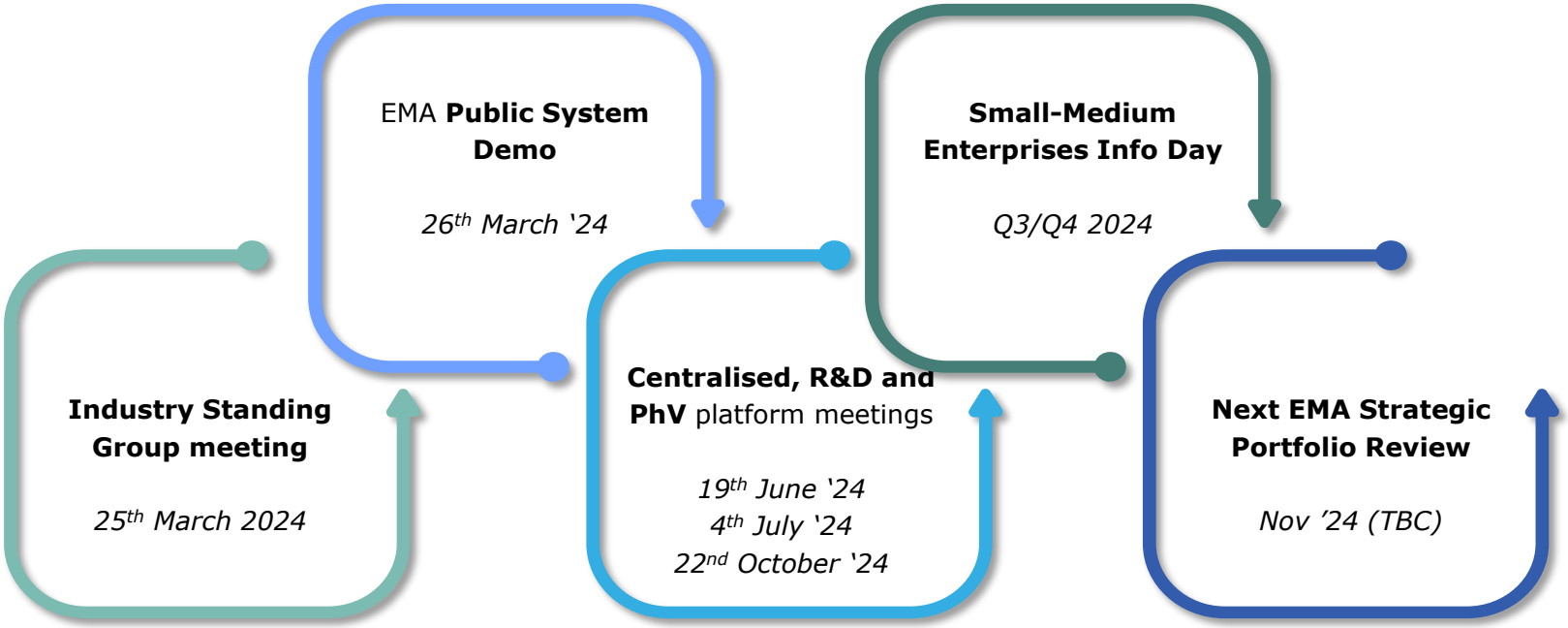
UAT activities

Development activities

Analysis & preparatory activities

Change Mgmt activities

# Industry Stakeholders engagement opportunities




# Any questions?