EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New Fee Regulation: upcoming changes foreseen for R&D Procedures

4 July 2024

Goal of the presentation & contents

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Provide an overview of:

- **The new fee regulation**
- **Changes and benefits for industry stakeholders, including operational details**

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Welcome

Jean Michel Mastio, Head of Finance Department, EMA

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Introduction and background to the New Fee Regulation

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

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Operational changes

Paola Samassa, Accounting Officer, EMA

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Engagement opportunities, Q&A and closing

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

Introduction and background to the New Fee Regulation

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

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

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Current state

Currently, fees levied by EMA are laid down in <u>two regulations</u>

- Council Regulation (EC) No 297/95 on the general fees for the Agency
- Regulation (EU) No 658/2014 for pharmacovigilance activities

→ **Need for harmonisation and updates**

Future state from 01 Jan 2025

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

The fees payable to the Agency

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

High-level changes and benefits for Industry (H)

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FEE CHANGES INCLUDING ADMIN FEES

- ✓ The **update of fee structures** which are calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA
- ✓ The **removal** of certain fees (e.g., for Type I variations and renewals)
- ✓ The **introduction of new fees** (e.g., for Pre-Submission, Referrals and re-examination of MA applications)
- ✓ The **modification of administrative fees** for withdrawal and for changes to the intended submission date

PAYMENT METHODS

- ✓ The **revision of payment methods and terms** for high-volume applications (e.g., Scientific Advice, Certificates and Parallel Distribution) introducing prepayment mechanism

Single framework for streamlined fee system

Simplification and **better understanding** of the fee system

Solid frame for **innovation** in the pharmaceutical sector through provisional incentives

Integration of applications and systems, improving the **corrections process** as well as increasing **automation**

Implementation timeline

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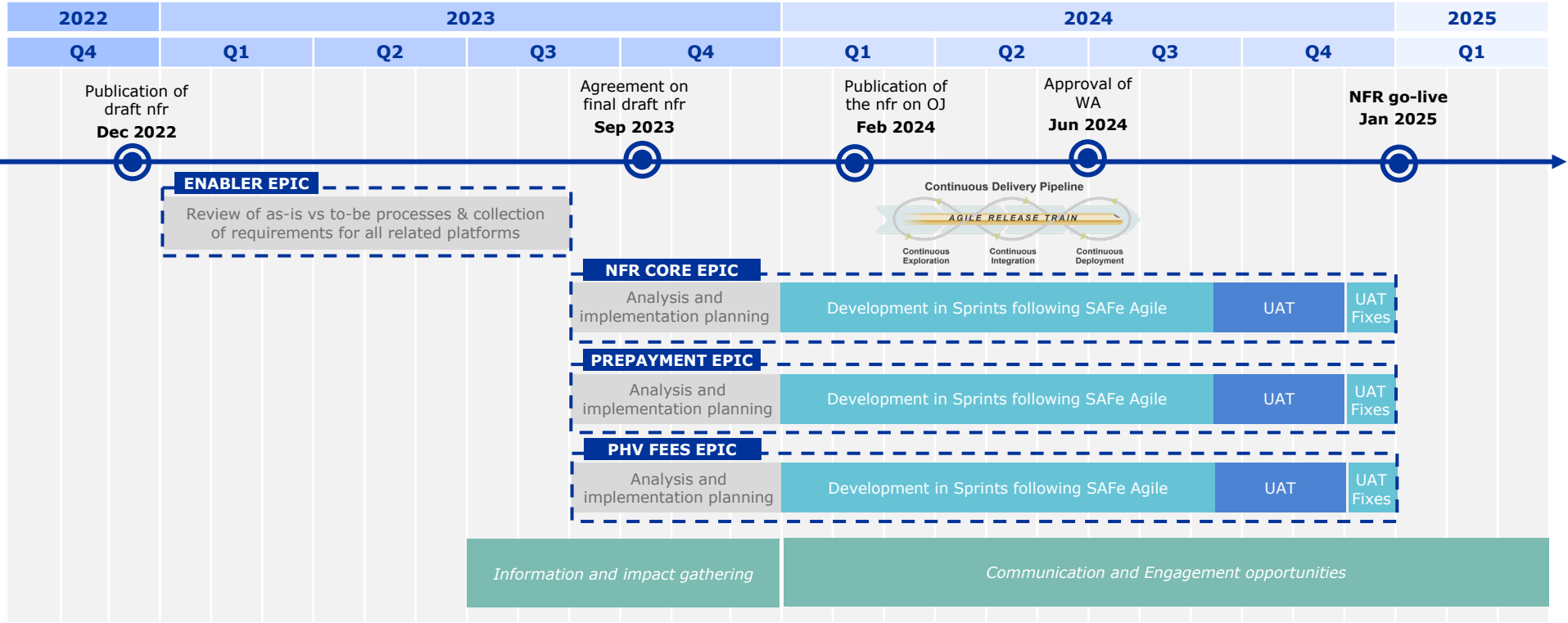

Acronyms

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

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 being updated based on the new fee regulation.

To ensure 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 (starting with the Working Arrangements in July 2024).***

Post meeting update: Published Working Arrangements

Fees payable to the European Medicines Agency | European Medicines Agency (europa.eu)

Operational changes

Paola Samassa, Accounting Officer, EMA

Main impacted procedures and related changes

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CURRENT

FROM 1ST JANUARY 2025

SCIENTIFIC ADVICE

- 3 basic fee levels based on areas of advice (quality, safety and clinical development), qualification process type and bioequivalence studies for generic medicines
- Different fee for initial- and follow-up advice
- Payment approx.45 days following start of procedure

- **No change** in fee levels and areas of advice
- **No distinction between initial- and follow-up** advice
- **Revision of payment methods and terms** (Prepayment)
- **Incentive for EEEA** (waiver)
- **Incentive for pandemic situations** (waiver)
- New **admin fee charge** for withdrawals between 24hrs after submission and start of procedure (validation period) and for negative validation
- New **penalty for false declaration**

Please note: this is not an exhaustive list of all fee changes, further details will be included in relevant guidance.

Main impacted procedures and related changes

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CURRENT

PAEDIATRICS APPLICATIONS

- No fee levied
- No NCA remuneration

ORPHAN DESIGNATION

- No fee levied
- No NCA remuneration

FROM 1ST JANUARY 2025

- The application **fee is introduced but waived**
- Remuneration of NCAs introduced (rapporteur)
- Affected processes: Initial PIP, modification of a PIP, compliance check, product specific waiver
- New **admin fee charge** for withdrawals between 24hrs after submission and start of procedure (validation period) and for negative validation

- The **application fee is introduced but waived**
- Remuneration of NCAs introduced (rapporteur)
- Affected processes: Application for OD and maintenance of OD
- New **admin fee charge** for withdrawals between 24hrs after submission and start of procedure (validation period) and for negative validation

Please note: this is not an exhaustive list of all fee changes, further details will be included in relevant guidance.

New payment process for Certificates and Scientific Advice

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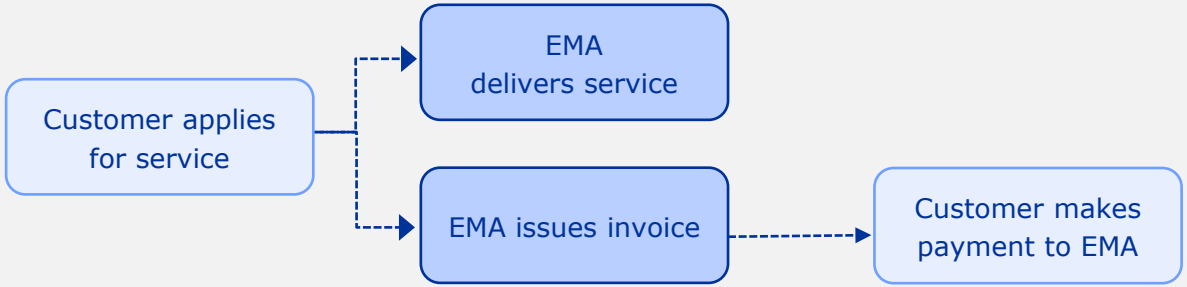
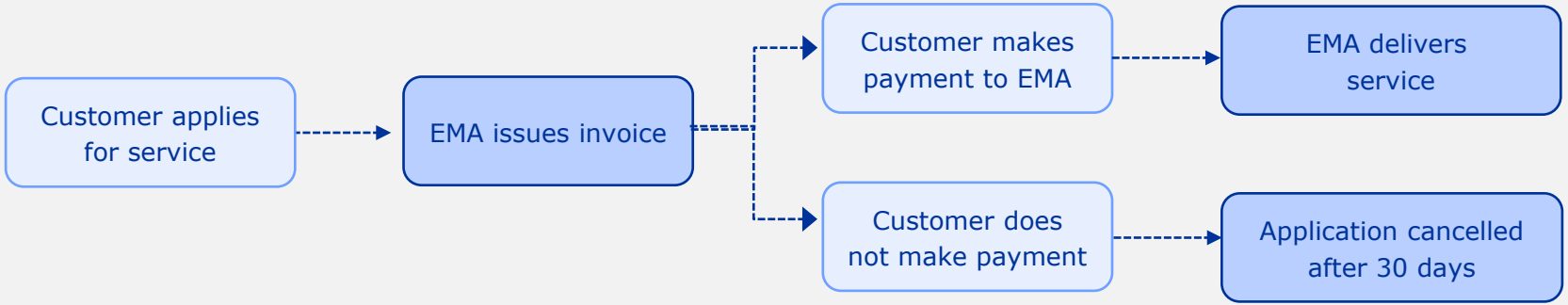
Current: provision of service is independent from charge having been paid



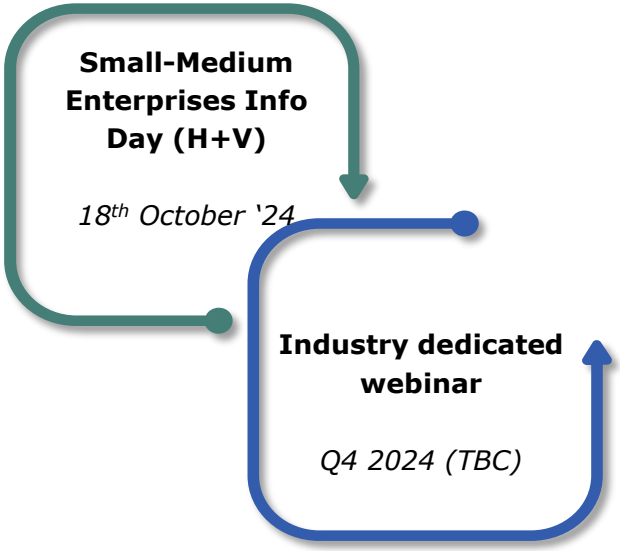
Future: provision of service only after charge has been paid in its entirety



Engagement opportunities, Q&A and closing

Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA

Industry stakeholders' engagement opportunities



Past events:

- **Industry Standing Group** (25/03/24): LINK
- **Public System Demo** (26/03/24): LINK
- **EMA/Affordable Medicines Europe bilateral meeting** (10/04/24): LINK
- **Public System Demo** (26/06/24): LINK

For any questions, please **email NFR@ema.europa.eu**

Other important information

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KEY TOPICS

Process to share key indicator information (e.g., EMA Annual Activity Reports)

These will be shared in accordance with **Article 10 and Annex VI** of the new Fee Regulation.

Sharing NCA budgetary information

This will be provided by NCAs in compliance with **Article 10 and Annex VI** of NFR. The methodology for collecting data from NCAs is being defined.

Consultation before publication of Special Reports

These will be made public but are not **subject to public consultation** before their adoption.