



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# New Fee Regulation: upcoming changes foreseen for Small and Medium-sized Enterprises (SMEs)

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Focus on: Human Medicinal Products

SME info day - 18 October 2024





**Provide an overview of:**

- **The new fee regulation**
- **Changes for SMEs, including operational details**

**1**

## **Introduction & background to the new fee regulation**

*Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA*

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## **Operational changes for SMEs**

*Claudia Galeazzo, Financial Technical Adviser, EMA*

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**Q&A**

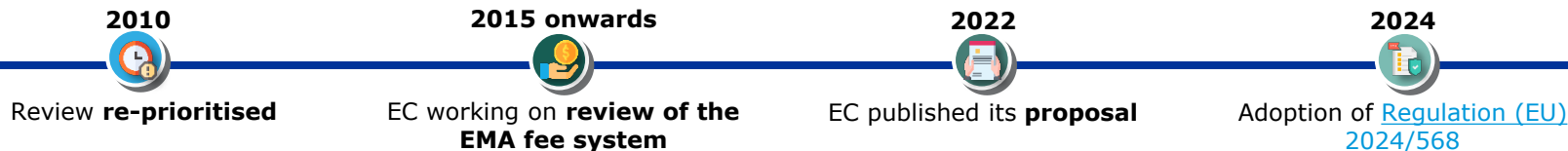


# Introduction & background to the new fee regulation

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*Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA*

## Timeline



**Future state from 01 Jan 2025**



A **single framework for a streamlined fee system** for the Agency



The fees payable to the Agency will be:

- **proportionate to the work** carried out reflecting **complex evaluations**;
- **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)

## FEE CHANGES INCLUDING ADMIN FEES



- ✓ The **simplification** of the fee calculation
- ✓ The **update of fee structures** now calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA
- ✓ The **modification of administrative fees** for withdrawal and for changes to the intended submission date

## REVISION OF PAYMENT METHODS



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

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

EMA's **documents**, user guides, web pages and FAQ documents are being updated based on the new fee regulation\*.

### Currently available documentation:

- [Current Fee regulations](#)
- [Explanatory note](#)
- [Implementing rules](#)
- [SME Regulation](#)  
(continues to apply)



### Documentation applicable starting from 1<sup>st</sup> January 2025:

- [Regulation \(EU\) 2024/568](#) provides information on:
  - Fees, charges and remuneration for both *human* and *veterinary* medicinal products, Annual fees (including Pharmacovigilance), Other Fees and charges and remuneration, Fee incentives (Annex 5) including SME provisions not covered by the SME Reg.
- [SME Regulation](#) provides:
  - Certain fee reductions and deferrals for SMEs
  - Administrative assistance (translations, SME office support and User Guide)
- [Working arrangements](#) include:
  - Clarifications on terminology and requirements, Fee reductions (Article 6.4), Payment modalities, Mechanisms for financial compensation of NCAs, list of fee due and applicable dates and deadlines for payments of remuneration to NCAs (appendix)
- [Fee Q&As on EMA's website](#)



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 **November 2024 (started with the Working Arrangements in July 2024)**.

\*Please note that specific Q&A documents including information on SMEs incentives will be available on EMA's website



# Operational changes for SMEs

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*Claudia Galeazzo, Financial Technical Adviser, EMA*

## CURRENT SME FEE REDUCTIONS:



- ✓ **Scattered in various legal provisions:** SME Reg, General Fee Reg, Pharmacovigilance fee Reg and complemented in the implementing rules

## FUTURE FEE REDUCTIONS:



- ✓ **2 legal basis** (SME Reg and NFR), aligned by the Working arrangements
- ✓ **Previous reductions maintained**
- ✓ **Clarity** and **alignment** on applicability



## CURRENT

### ***PRE-SUBMISSION ACTIVITIES (related to MAA)***

- No application fee



## FROM 1ST JANUARY 2025

- 1 pre-submission activities fee due at submission of Letter of Intent
- 1 additional fee each time the intended submission date is changed by more than 60 days
- **No SME incentive**

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### ***PAEDIATRICS APPLICATIONS (PIP, compliance check)***

- No application fee

- No application fee
- New admin fee charge of 4.400 EUR if application is withdrawn more than 24hrs after submission and before start of procedure (validation period) or rejection upon validation – **Charge waived for SMEs**

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



## CURRENT

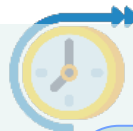
### **ORPHAN DESIGNATION**

- No application fee

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### **Administrative Charges**

- 1 fee for an administrative charge



## FROM 1ST JANUARY 2025

- No application fee
- New admin fee charge of 4.400 EUR if application is withdrawn more than 24hrs after submission and before start of procedure or rejection upon validation – **Charge waived for SMEs**

- New admin fee charge if any application is withdrawn more than 24hrs after submission or rejection upon validation – **Charge waived for SMEs**

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



## **INITIAL MARKETING AUTHORISATION APPLICATION**



### CURRENT

- 3 levels of basic fees with separate fees for additional strength or form and presentation

### FROM 1ST JANUARY 2025

- 9 different fee levels (based on legal basis) with no separate fee for additional strength or form and presentation
- Fee range: EUR 33.300 – 865.200
- Valid SME status at the time of submission\*

**SME incentive:** fee deferral for SMEs until the outcome of MAA and 100% fee reduction for designated orphan products applied by a valid SME

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

*\*Detailed rules for the application of SME incentives set out in the working arrangements and related Q&As*



## **RE-EXAMINATION OF PROCEDURES**

### CURRENT

- Currently, no fee charged



### FROM 1ST JANUARY 2025

- New fee for re examination of procedure (30% of initial) – **No SME incentive**

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



## CURRENT

### **ANNUAL FEE**

- Currently 3 fee levels



## FROM 1ST JANUARY 2025

- **3 fee levels but amount increased:**  
range from 60.300€ to 232.400€

**SME incentive:** 40% fee reduction for SME and 100% for micro sized companies\*

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



## CURRENT

### **VARIATIONS**

- 5 fee levels
  - 3 for major variation of type II
  - 2 for minor variations of type I
- 4 charges for work-sharing



## FROM 1ST JANUARY 2025

- **2 fee levels:** one for Type II extension of indication (one higher fee, 163.200€) and one for all the other Type IIs (heavily reduced fee, 22.000€)
- No fees for minor variations and type I (activity included in annual fee)
- **1 charge for work-sharing** of major variation of type II
- No capping for groupings of Type IIs

**SME incentive:** 40% fee reduction for SME and 100% for micro sized companies

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



## CURRENT

### **EXTENSIONS OF MA**

- 3 levels of basic fees with separate fees for additional strength or form and presentation

### **REFERRALS**

- 5 different fee levels, only applicable to PHV referrals



## FROM 1ST JANUARY 2025

- 3 fee levels and no separate fee for additional strength or form and presentation

- 9 different fee levels including PHV and non PHV
- 3 types of referrals legal basis will be waived, and therefore not subject to a fee
- The referrals subject to a fee will be calculated via the chargeable units
- No possibility to declare SME status after the referral is notified or after invoice is received

**SME incentive:** 40% fee reduction for SME and 100% for micro sized companies



## CURRENT

### **CERTIFICATES**

- Provision of service is independent from fee having been paid



## FROM 1ST JANUARY 2025

- Provision of service only after fee has been paid in its entirety upon submission of request.

**SME incentive:** 100% fee reduction for SME provided they have a valid status at submission

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



## **SCIENTIFIC ADVICE** **CURRENT**

- 6 basic fee levels
- Separate fee for initial- and follow-up advice
- Distinction between quality, safety and clinical development, qualification and bioequivalence studies
- **SME status** needs to be valid by the time the SA procedure starts (SA request can be submitted while the SME status is pending)



## **FROM 1ST JANUARY 2025**

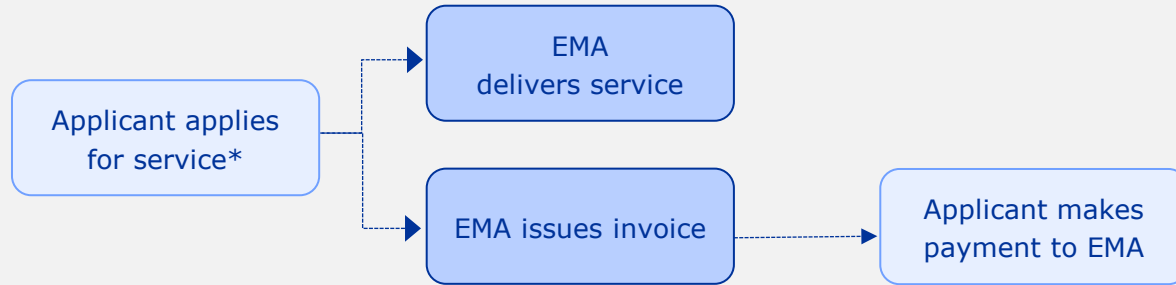
- 3 fee levels
- Fee range: EUR 51.900 - 98.400
- No distinction between initial and follow-up advice
- Distinction between quality, non-clinical, clinical development, qualification, bioequivalence studies and novel methodologies
- Revision of payment methods and terms (prepayment)
- **SME status** needs to be valid at the time of submission, otherwise the incentive will not apply\*

**SME incentive:** 90% fee reduction for SME / 100% fee reduction for designated orphan products

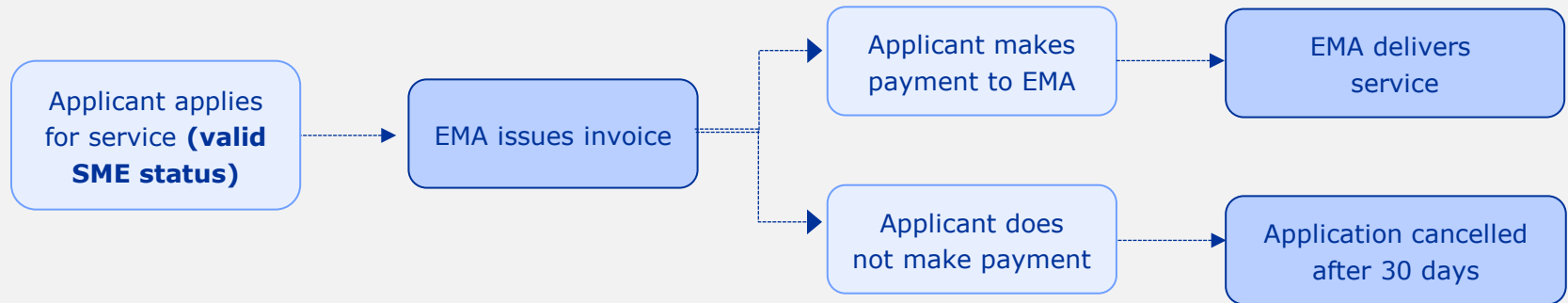
*Please note: this is not an exhaustive list of all fee changes, further details are included in relevant guidance.*



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



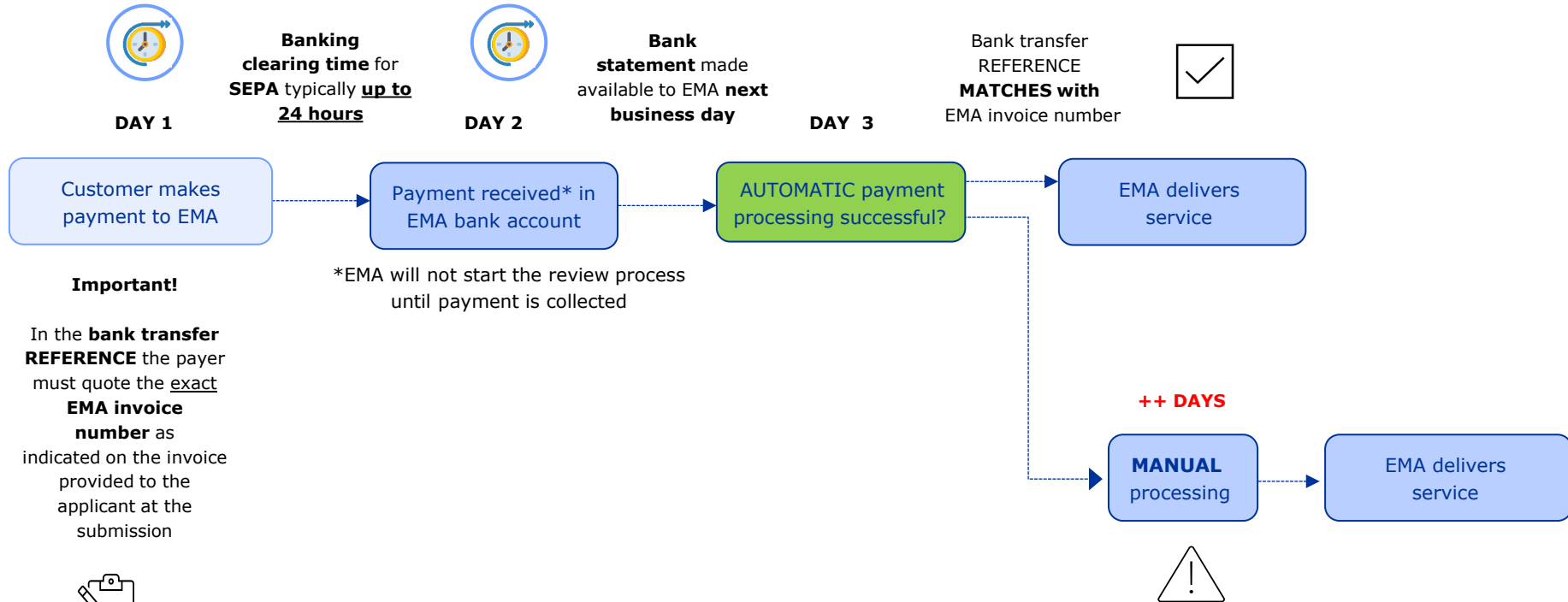
**Future:** provision of service only after fee or charge has been paid in its entirety



\*SA, certificates



## Expected timelines for allocation of payments





Increase of **MAA fees**

**Scientific Advice fees** reduced (No distinction between initial and follow-up advice)

**New fees** for **re-examination** of MA procedures and **pre-submission activities**

New **pre-payment method for Scientific Advice and Certificates**

**SME status** must be valid at the time of submission\*

EMA explanatory notes will be replaced by **Q&As on fees** to be published in **November 2024**

All current **provisions in terms of SME fee incentives will still apply**

## Available Guidance



- [NFR text](#)
- [Working Arrangements](#)
- [EMA webpage on payable fees](#) (including Q&A document)
- [EMA webpage on support to SMEs](#)

## Past events



- [Q1 Public System Demo](#) (26/03/24)
- [Q2 Public System Demo](#) (26/06/24)
- [Q3 Public System Demo](#) (18/09/24)

## Coming up



- [Webinar for Industry stakeholders](#) (24/10/24)
- Q4 Public System Demo (12/12/24)



For any questions, please email [NFR@ema.europa.eu](mailto:NFR@ema.europa.eu)