EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New fee regulation

Informative webinar for the human industry

Presented on 24 October 2024

Agenda

1	**Introduction & background to the new fee regulation** *Jean Michel Mastio, Head of Finance Department, EMA*	**10.30 – 10:35 CEST**
2	**Main changes applicable to Human procedures** *Claudia Galeazzo, Financial Technical Adviser, EMA*	**10.35 – 10:55 CEST**
3	**Overview of financial aspects related to the new fee regulation** *Paola Samassa, Accounting Officer, EMA*	**10:55 – 11:10 CEST**
4	**Closing and Q&A session**	**11:10 – 11:30 CEST**

Introduction & background to the new fee regulation

New fee regulation background and new state from 1st Jan 2025

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Timeline

2010
Review due but **re-prioritised**

2015 onwards
EC working on **review of the EMA fee system**

2022
EC published its **proposal**

2024
Adoption of Regulation (EU) 2024/568

Future state from 01 Jan 2025

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

Solid frame for innovation in the pharmaceutical sector, e.g. through incentives for SMEs, entities not engaged in economic activities, pandemic situation, immunological veterinary medicinal products.

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)
- will **reflect the complex evaluations** and **recognise the contributions from Member States'** competent authorities necessary to obtain and maintain a Union authorisation

High-level changes for the human industry

- **Simplification** of the fee calculation
- **Update of fee structures** now calculated per procedure and based on actual costs incurred across 29 EEA Member States and EMA
- **Introduction of administrative charges** for withdrawal and for changes to the intended submission date
- **Revision of payment methods and terms** for high-volume applications *(e.g., scientific advice, certificates and parallel distribution)* introducing prepayment mechanism
- **Removal of certain fees** *(e.g., for Type I variations and renewals).*
- **Introduction of new fees** *(e.g., for Pre-Submission, Referrals and re-examination of MA applications / opinions)*

Main changes applicable to Human procedures

Procedures impacted by major changes (1/6)

CURRENT

FROM 1ST JANUARY 2025

SCIENTIFIC ADVICE *(NFR, Section 1 of Annex I)*

•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)

•3 fee levels
•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*

INITIAL MAA *(NFR, Section 2 of Annex I)*

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

- *9 different fee levels (based on legal basis) with no separate fee for additional strength or form and presentation*
- *Valid SME status at the time of submission*
- *New fee for re examination of procedure (30% of initial)*

Procedures impacted by major changes (2/6)

CURRENT

FROM 1ST JANUARY 2025

EXTENSION OF MARKETING AUTHORISATION *(NFR, Section 4 of Annex I)*

- 2 levels of basic fees
- Separate fees for additional strength, pharmaceutical form and presentation

- *3 levels of fees;*
- *Each fee is applicable to a single pharmaceutical form associated with a single associated strength*

CERTIFICATION OF A MEDICINAL PRODUCT (PMFs and VAMFs) *(NFR, Section 8 and 9 of Annex I)*

- *3 fee levels*

- *4 different fee or charge levels*

Procedures impacted by major changes (3/6)

CURRENT

FROM 1ST JANUARY 2025

RE-EXAMINATION OF PROCEDURES *(NFR, Section 5 of Annex I)*

- Currently not charged

- *1 fee equivalent to 30 % of the fee applicable to the initial opinion*
- *No SME incentive*

VARIATIONS *(NFR, Section 6 of Annex II)*

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

- *2 fee levels (Type II extension of indication and other Type IIs)*
  - *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*

Procedures impacted by major changes (4/6)

CURRENT

FROM 1ST JANUARY 2025

REFERRALS *(NFR, Section 6 of Annex I)*

- 5 fee levels

- *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*
- *For 3 types of referrals the fee is waived*

PARALLEL DISTRIBUTION *(NFR, Section 6.3 of Annex IV)*

- Difference between initial notification, annual update notification (manual/automated check)

- *Change in fee structure. Pharmaceutical form is removed from grouping logic. Annual updates will be submitted per product and member state of destination.*
- *Revision of payment methods and terms* ***(prepayment)***

Procedures impacted by major changes (5/6)

CURRENT

FROM 1ST JANUARY 2025

PRE-SUBMISSION ACTIVITIES *(NFR, Section 3 of Annex IV)*

- Currently, no fee charged

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

INSPECTIONS *(NFR, Section 1 of Annex IV)*

- No formal communication to MAHs as to start of inspection

- *New process to communicate to MAH the first day of inspection*
- *Different fees charged if inspection is outside or within EU.*
- *Fees and charges now apply for cancellation. Different amount if cancellation happens before 30 day or after 30 days*

Procedures impacted by major changes (6/6)

CURRENT

FROM 1ST JANUARY 2025

CONSULTATION ON MEDICAL DEVICES *(NFR, Section 7 of Annex IV)*

- No clear provisions included for ancillary substance
- No provision for MD with absorbed substances and companion diagnostic

Current practice :

- Ancillary medicinal substance:
- 3 fee levels for initial request
- 3 fee levels for follow-up
- Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose:
- 1 fee level

Companion diagnostic:

- 3 fee levels (initial consultation, additional AS, follow-up)

- *Ancillary medicinal substance:*
- *2 fee levels for initial request*
- *1 fee level for change*
- *MD with absorbed substances and companion diagnostic are included with same provisions as current practices*

Procedures impacted by minor changes

CURRENT	FROM 1ST JANUARY 2025
***PSUR** and **PASS** (NFR, Section 15 of Annex I)*	
• Currently charged	• *Changes to fee amounts*
***ANNUAL FEE** (NFR, Section 1 of Annex III)*	
• Currently 3 levels of annual fees and several reductions in place	• *3 different levels of fees, changes to fees amount, reductions apply as current*
***ANNUAL PHV FEE** (NFR, Section 3 of Annex III)*	
• Currently charged	• *Changes to fee amounts*
***PAEDIATRICS APPLICATION** and **ORPHAN DESIGNATION** (NFR, Section 11 and 12 of Annex I)*	
• No fee levied • No NCA remuneration	• *The application fee is introduced but waived* • *Affected processes for **Paediatrics**: Initial PIP, modification of a PIP, compliance check, product specific waiver* • *Affected processes for **Orphan**: Application for OD and maintenance of OD*

Newly introduced administration fee

Main change

From 1st January 2025, a **new admin fee charge of 4.400 EUR** will be applied if the application is withdrawn more than 24hrs after the submission and before the start of procedures (validation period).

Main impacted procedures

- *Scientific advice*
- *Initial Application of a MA*
- *Extension of MAA*
- *Paediatric applications*
- *Orphan designation*
- *Scientific Opinions*
- *PMF*
- *VAMF*
- *Variations*

Overview of financial aspects related to the new fee regulation

General provisions applicable to all services and specific provisions applicable only to services subject to prepayment

Content

Receiving an invoice

- **Due dates for fees and charges**
- **Customer account number legal address / billing address**
- **Invoice numbering, content and applicant/MAH reference number (PO)**
- **EMA Invoicing Portal**

Paying an invoice

- **Deadline for payment (invoice due date)**
- **Payment by bank transfer**
- **Remittance advice**
- **Payment processing time**
- **Consequences of late/non-payment**
- **Credit balances and refunds process**

Raising a query

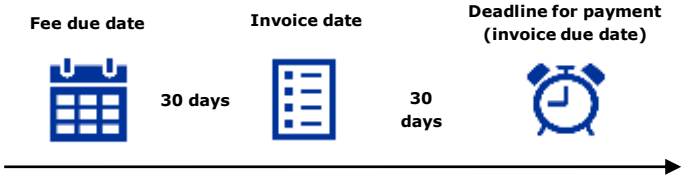
- **How to raise a query on an invoice**
- **Agency's procedure for handling invoice queries**

Specific provisions applicable only to services subject to **prepayment**
(**Scientific Advice, Parallel Distribution and Certificates**)

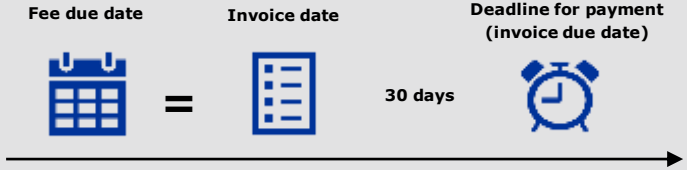
Receiving an invoice from the Agency (1/2)

Due dates for fees and charges

- Due dates are established in the **Fee Regulation's Working Arrangements** (Appendix)
- **A fee or a charge is 'due'** when it becomes payable by the applicant
- The fee due date **triggers the issuing of an invoice** by the Agency within 30 days to the applicant/MAH
- The **invoice** then **payable by the applicant/MAH within 30 days** from the issue date



Specific provisions applicable to prepayment



Customer account number legal address / billing address

- The **Customer Account Number** is a **unique reference number** for financial matters. It starts with 5 (PD) or with 6 (MAH) and it is quoted (selected) by the applicant at the point of submission
- The Agency issues an invoice to the **applicant/MAH legal address.**
- It is possible to specify a **billing address** if the applicant/MAH wishes to receive all invoices to a different address than the legal address.
- The invoice is sent **by email** to the **designated financial contact point(s)** and/or it can be **downloaded** from the **EMA Invoicing Portal**
- **Important!** Keep **billing addresses and contact information up-to-date** for smooth EMA-MAH communication

Specific provisions applicable to prepayment

- Service delivery dependent of payment having been received
- Importance of **internal communication** between regulatory and financial contact point within the applicant/MAH's organization
- Financial contact points **encouraged to register** with the EMA Invoicing Portal

Receiving an invoice from the Agency (2/2)

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Invoice numbering, content and applicant/MAH reference number (PO)

- **Invoice numbering** starts with 7 (MA fees) and with 8 (PhV fees)
- **Details** of the MA procedures and PhV chargeable units (CU) line listings
- **Purchase Order numbers** (PO) or similar **references** can be quoted on the invoice provided they are communicated in advance by the applicant/MAH to EMA at the submission point (or as 'blanket PO' applicable across all procedures)
- **Important!** Applicants/MAH adopting 'No PO No PAY' policy to ensure **validity of the PO numbers** provided to EMA
- EMA encourages the issuing of an exception to the policy for EMA
- The Agency does not have an economic activity and therefore does not have a **VAT number**

Specific provisions applicable to prepayment

- Invoices numbering for **prepayment** services starts with **9**
- Applicant/MAH '**No PO no PAY**' policy can **delay** the processing of the application

EMA Invoicing Portal

- Self-service tool allowing applicant/MAH(s) instant access to their account with EMA
- View and print-out new and copies of invoices
- View payments made
- Manage billing addresses
- Raise queries on invoices
- Link for registration on EMA How to Pay page

Specific provisions applicable to prepayment

- **Financial Information screen in IRIS** with invoice and payment information but not the PDF invoice
- Financial contact points **encouraged to register** with the EMA Invoicing Portal

Paying an invoice to the Agency (1/3)

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Deadline for payment (invoice due date)

- The deadline for payment is the 'payable by' date indicated on the invoice i.e. **30 calendar days from the invoice date**
- Ten days before the deadline EMA sends **(pre)reminder** that the deadline is approaching to the **designated financial contact point(s)**

Specific provisions applicable to prepayment

- In the case of Scientific Advice the Agency recommends **paying the invoice as soon as possible upon its receipt** for inclusion of the related submission in the next available start of procedure

Payment by bank transfer

- **Agency's bank account details** are quoted on the invoice and published on EMA website
- **Bank charges borne by the payer**. For non-SEPA payment instructions select 'OUR' to avoid deduction of bank charges

Specific provisions applicable to prepayment

- **Requirements** for bank transfers related to prepaid services:
  - One remittance (i.e. single payment) for each individual invoice
  - Full amount in Euro, no deductions (bank charges, others)
  - Invoice reference (full number starting with 9) clearly indicated in the bank transfer reference field
- **Bank transfers executed following the above rules will ensure straight through allocation of payment**

Paying an invoice to the Agency (2/3)

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Remittance advice

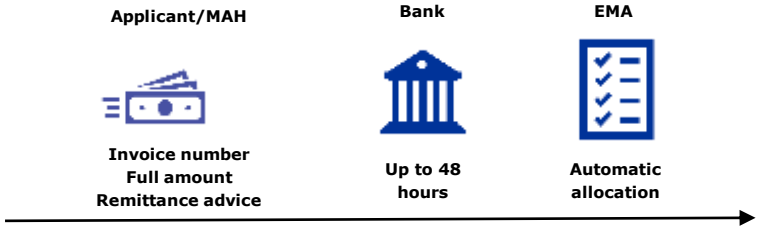
- Mandatory remittance advice in case multiple invoices are paid with one remittance (i.e. it requires manual allocation by EMA)
- In case of missing payment references, Agency contacts applicant financial contact point for confirmation of reason for payment (i.e. invoice number)

Specific provisions applicable to prepayment

- Mandatory **confirmation of payment execution** (date, amount and invoice number) to accountsreceivable@ema.europa.eu
- In case of unclear payment reference, Agency will contact immediately the applicant financial contact point requesting
- **Quick turnaround time** for resolution to avoid delays in processing the application

Payment processing time (allocation of receipts)

- Applicant makes the payment (SEPA credit transfer)
- **Up to 48 hours** banking clearing time and availability of bank statement to EMA
- EMA performs an automatic allocation of payments (receipts) to the corresponding invoices



Specific provisions applicable to prepayment

- **IRIS: Financial Information screen** updated in real time, confirming that the payment has been received
- **Certificates:** notification confirming the payment has been received will be sent by email to the requestor

Paying an invoice to the Agency (3/3)

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Consequences of late/non-payment

- Payment reminders, emails, calls, letters (**dunning**) sent by EMA accounting team
- Financial regulation contains provisions for late payment **interest** and enforced recovery
- Fee regulation contains provisions for **suspension of** evaluation **services** in case of no payment

Specific provisions applicable to prepayment

- If the payment is not received by the deadline for payment i.e 30 days from the date of the invoice, both **application and invoice** will be **cancelled**
- An **administrative charge** is applicable for Scientific Advice
- IRIS: Financial information screen will be updated with status of invoice and payment (not received)
- No payment reminders are sent past the deadline, only a (pre)reminder ten days before the deadline

Credit balances and refunds process

- **EMA owes an amount to the applicant/MAH** as a result of a credit note or an overpayment
- Credit balances are either **offset** against future invoices **or returned** to the payer
- **Refunds** are sent by default to the bank account from where the original payment was made
- Refunds to different bank account are possible e.g. when the original bank account is no longer open. Require production of additional supporting documentation and are subject to EMA 'call back' verifications

Specific provisions applicable to prepayment

- Payments received after the invoice and application have been cancelled will be automatically refunded
- It will **not** be **possible to offset** these payments against future applications

Raising a query on an invoice

How to raise a query on an invoice

- As soon as possible upon receipt of the invoice
- Queries on invoices shall be raised **via EMA Invoicing Portal** to ensure creation of a dispute case and efficient internal escalation
- Queries on invoices received by email to any Agency's email address are redirected to the EMA Invoicing Portal
- General queries not related to an invoice shall be raised via the usual EMA established channels (e.g. Ask EMA) for triaging
- Pre-invoice queries are important as they help to address potential issues before a fee invoice is issued

Agency's procedure for handling invoice queries

- A query **does not suspend the payment period** and the invoice still needs to be paid by its due date
- Disputes on the ground of **Purchase Order number not provided**/not valid are not accepted, i.e. **no reissuing of invoices**
- Disputes on **changes to billing address** not provided timely are not accepted, i.e. **no reissuing of invoices**

Specific provisions applicable to prepayment

- **Preventive** checks on validity of PO numbers and billing addresses
- **No PO no PAY'** policy can **delay** the processing of the application

Example of EMA invoice

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Applicant / MAH
LEGAL ADDRESS

Applicant / MAH
BILLING ADDRESS

Invoice 900XXXXXX

Date: 06.01.2025
Payable by: 05.02.2025

Your Account: 6XXXXX
Your VAT number:
Additional Reference:

The European Medicines Agency is exempt from VAT as per Protocol on the Privileges and Immunities of the European Communities.

Item	Material Description Application Number Product Name Site	Customer Ref.	Amount	Cur.
1	DETAILS OF TYPE OF PROCEDURE	**REF/PO NUMBER** provided by Applicant/ MAH	100.000,00	EUR
		TOTAL	**100,000.00**	**EUR**

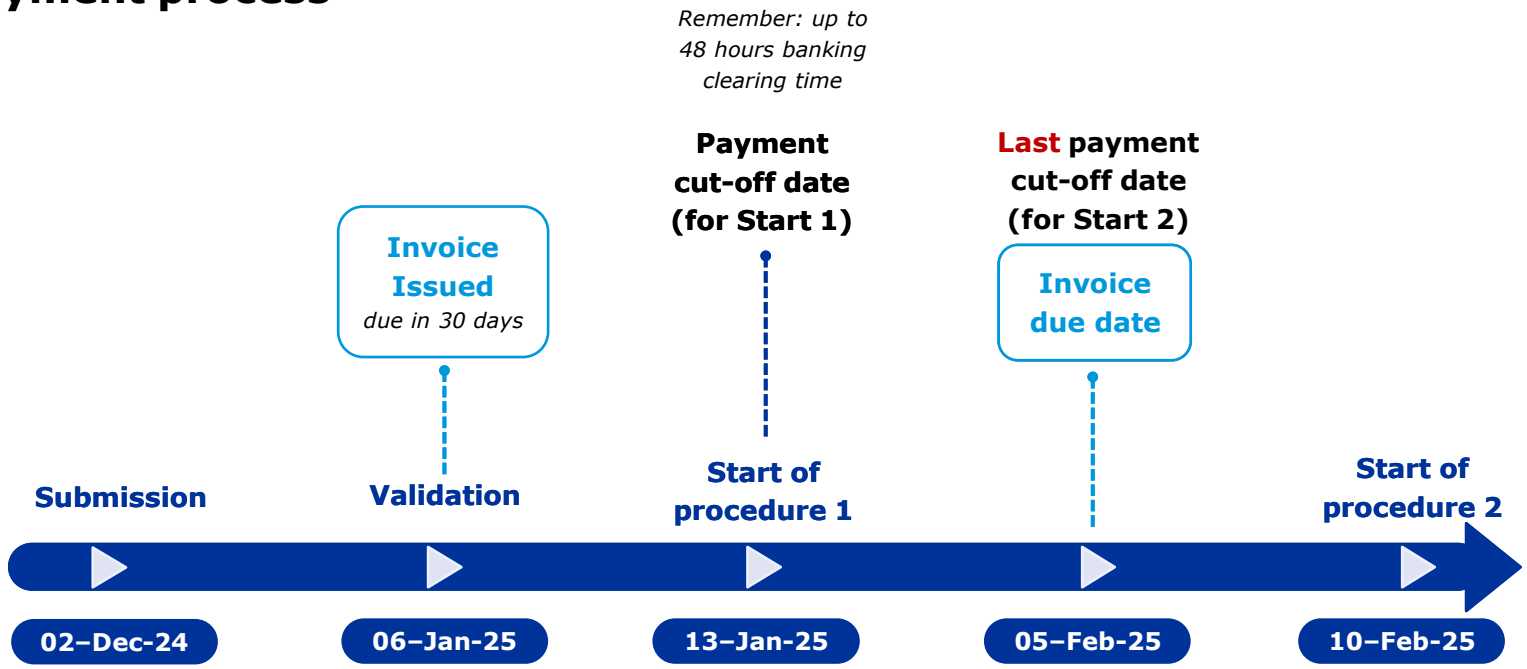
Payment by bank transfer only to: ABN AMRO BANK N.V.
• **IBAN** NL33ABNA0837286506 • **SWIFT** ABNANL2A • Please quote our invoice number on the bank transfer

Domenico Scarlattilaan 6 • 1083 HG Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000 **Website** www.ema.europa.eu

An agency of the European Union

Human scientific advice key dates*

Pre-payment process



*Example with submission date 02-Dec-24 (without preparatory meeting)

Key takeaways to ensure straight-through processing of EMA invoices

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Receiving an invoice

- EMA Fees **Working Arrangements** (due dates, when to expect what, fee levels, etc.)

- **Billing addresses** up to date
- **PO references** valid
- Dedicated **contact points** for financial matters
- **Internal communication** regulatory/financial contact points

- Register with the **EMA Invoicing Portal**

Paying an invoice

- Compliance with **'invoice due date'** to avoid cancellations (for prepayment services) or late payment interest

Bank transfers requirements

- EMA invoice number in reference field
- Full amount
- One single payment per invoice (for prepayment)
- Send us a remittance advice

New

Implementation of SEPA Direct Debit being evaluated (Q22025)

Raising a query

- **Preventive checks** on billing addresses and validity of PO numbers **prior to receiving an invoice**

- Queries on an invoice to be **raised as soon as possible** after its receipt via EMA Invoicing Portal

Coming soon

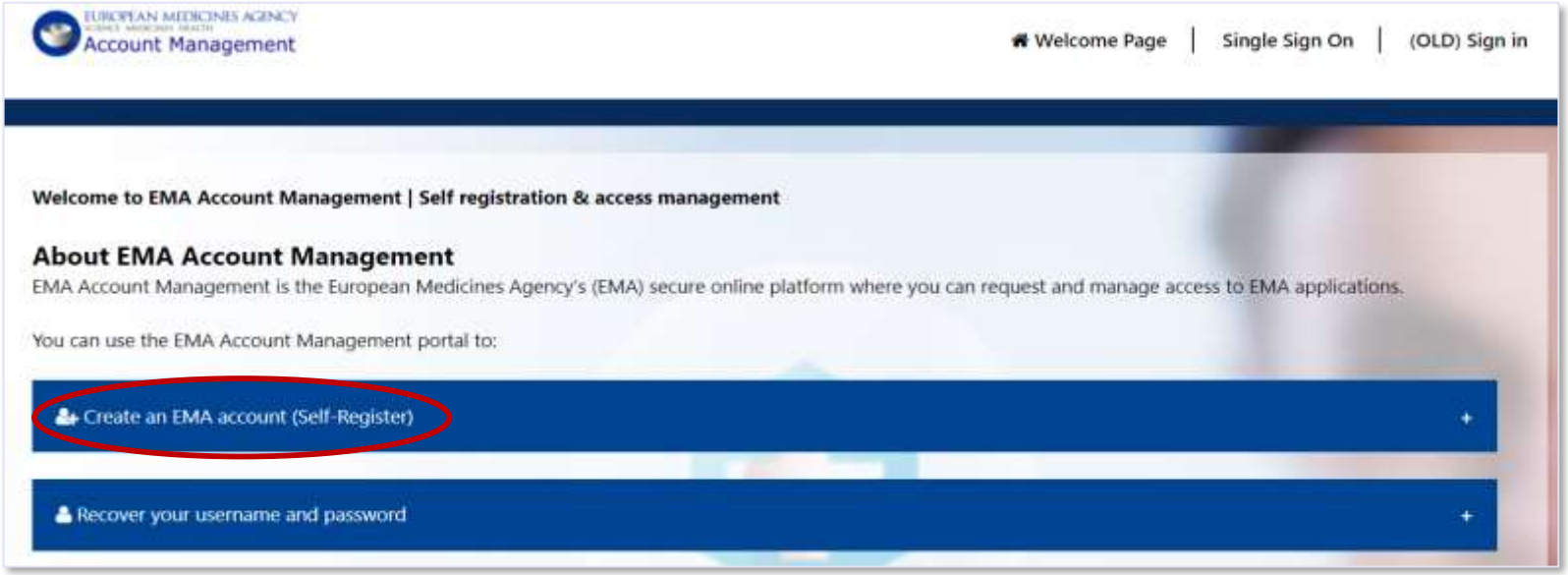
How to pay webpage content update

Closing and Q&A session

Register now on EMA Account Management to request certificates

MAHs must have a **valid EMA account** in order to **request *certificates*** from 1st January 2025, as the request will be sent via a **webform** as opposed to the currently used pdf form sent via email. Further details on the new webform will follow via email.

To register, please follow instructions here and for further information consult this webinar.



Updates to available regulatory guidance

Documents are being updated and will be made available on EMA's website in November 2024 (Working Arrangements already published)

Currently available documentation:

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

Documentation applicable starting from 1st January 2025:

- Regulation (EU) 2024/568
- SME Regulation
- Working arrangements
- Fee Q&As on EMA's website

Industry stakeholders' engagement opportunities

Public System Demo

12 December 2024

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