



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New fee regulation

Informative webinar for the veterinary industry

Presented on 24 October 2024

An agency of the European Union



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Introduction and background to the new fee regulation

Ivo Claassen, Head of Veterinary Medicines Division, EMA

2

Understanding the new fee regulation;

Chargeable units and their use

Anna Vecellio, Veterinary Planning and Reporting Specialist, EMA

3

Overview of financial aspects related to the new fee regulation

Paola Samassa, Accounting Officer, EMA

4

Closing and Q&A session



09:30 – 09:35 CEST

09:35 – 09:55 CEST

09:55 – 10:10 CEST

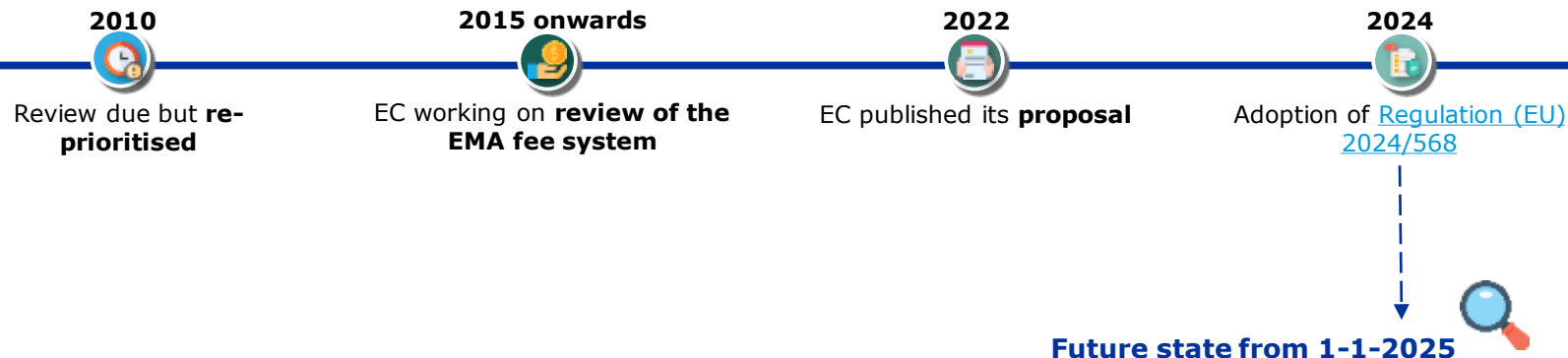
10:10 – 10:30 CEST



Introduction and background to the new fee regulation



Timeline



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

- **Simplification** of the fee calculation
- **Update of fee structures** now calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA
- **Modification of administrative fees** 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 variations requiring assessment with reduced timetable*)
- **Introduction of new fees** (*e.g., for Pre-Submission, Referrals and re-examination of opinions*)
- **Introduction of a pharmacovigilance annual fee** for veterinary nationally authorised products
- **Revision of the methodology to apply incentives** for veterinary medicinal products' procedures



Understanding the new fee regulation

Available resources

Legal act

[Regulation \(EU\) 2024/568](#)

- Annex II – Fees for veterinary medicinal products
- Annex III – Annual fees
- Annex IV – Inspections and administrative fees
- Annex V – Reductions

EMA website

- [EMA fees webpage](#)
- [Working arrangements document](#)
- NFR Q&As section

Other

[Webinar for veterinary industry on the new fee regulation](#), held on 20 June 2024



Chargeable units and their use

Deep-dive

[Regulation \(EU\) 2024/568](#), Art. 2

(2) 'chargeable unit in relation to veterinary medicinal products' means a unit defined by the **unique combination** of the following data fields contained in the Union product database established pursuant to Article 55(1) of Regulation (EU) 2019/6:

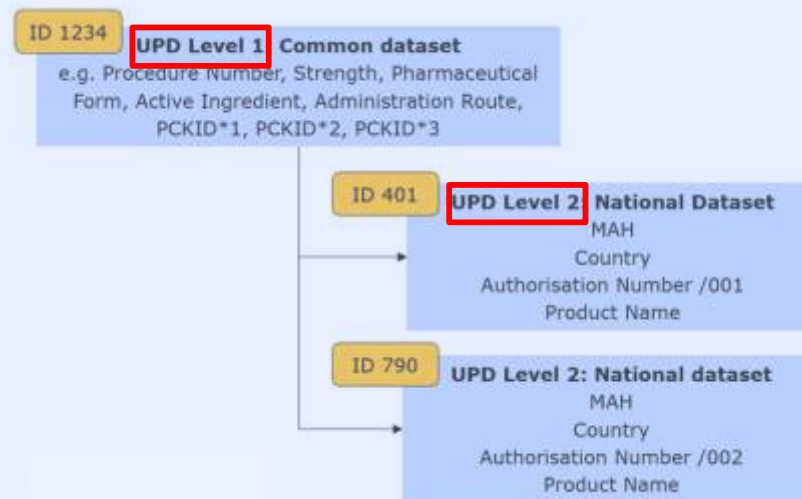
(a) the **Permanent Identifier** referred to under Data Field ID 3.1 in Annex III to Implementing Regulation (EU) 2021/16;

(b) the **Product Identifier** referred to under Data Field ID 3.2 in Annex III to Implementing Regulation (EU) 2021/16;

UPD level 1 = Product identifier

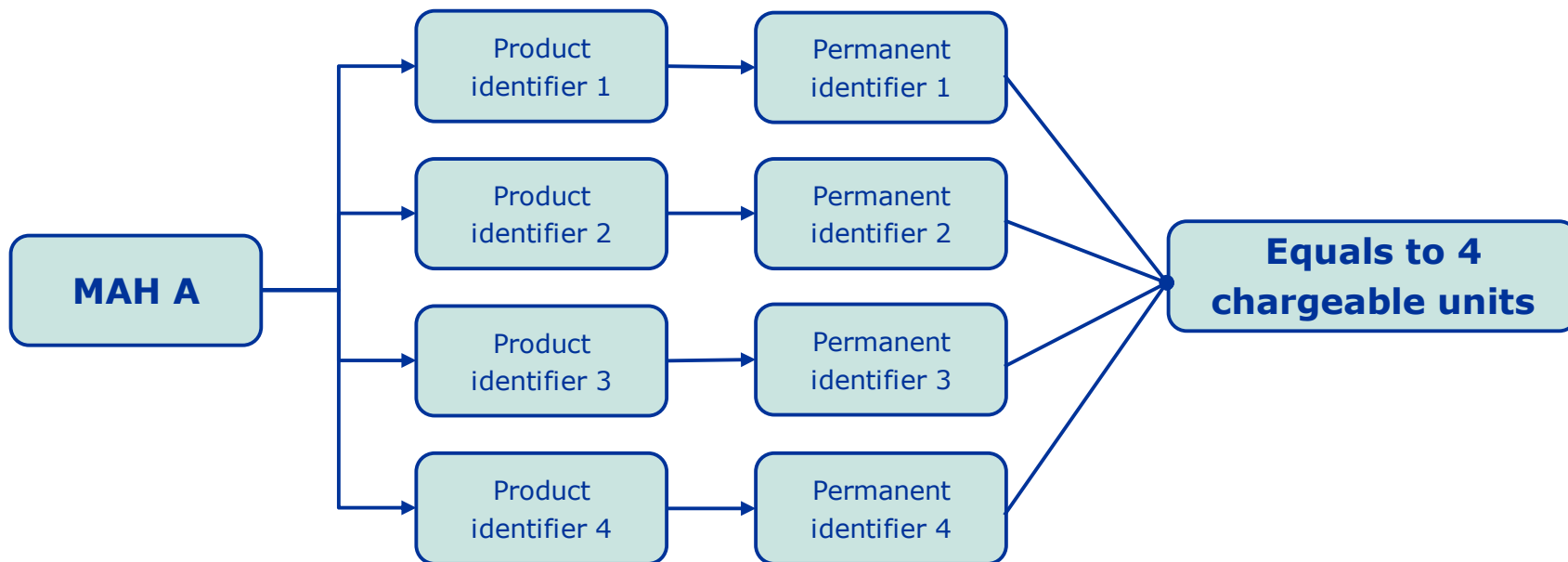
UPD level 2 = Permanent identifier

[EU Implementation Guide \(IG\) on veterinary medicines product data - Chapter 2: Format for the electronic submission of veterinary medicinal product information](#)



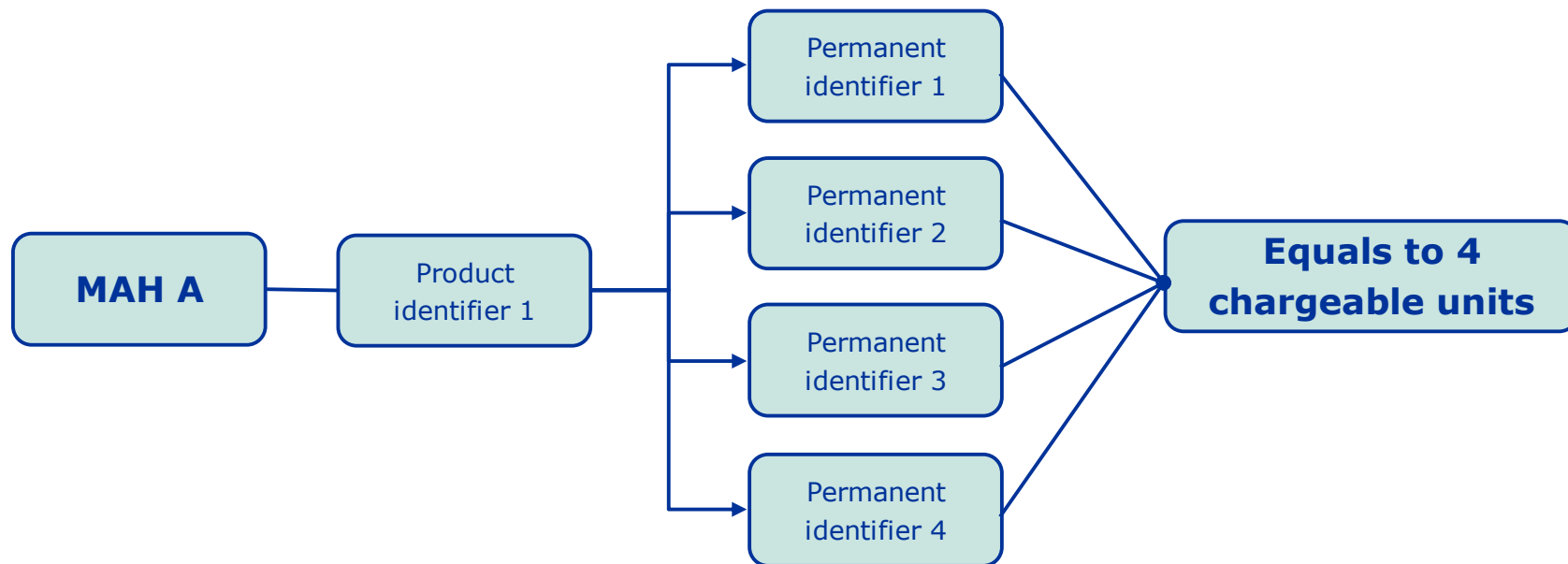
Use case 1

MAH A has **one** 'purely' nationally authorised product (NAP) with **four** different product identifiers and **four** different permanent identifiers (e.g., same substance and pharmaceutical form, **but** different strengths) = **4 chargeable units**



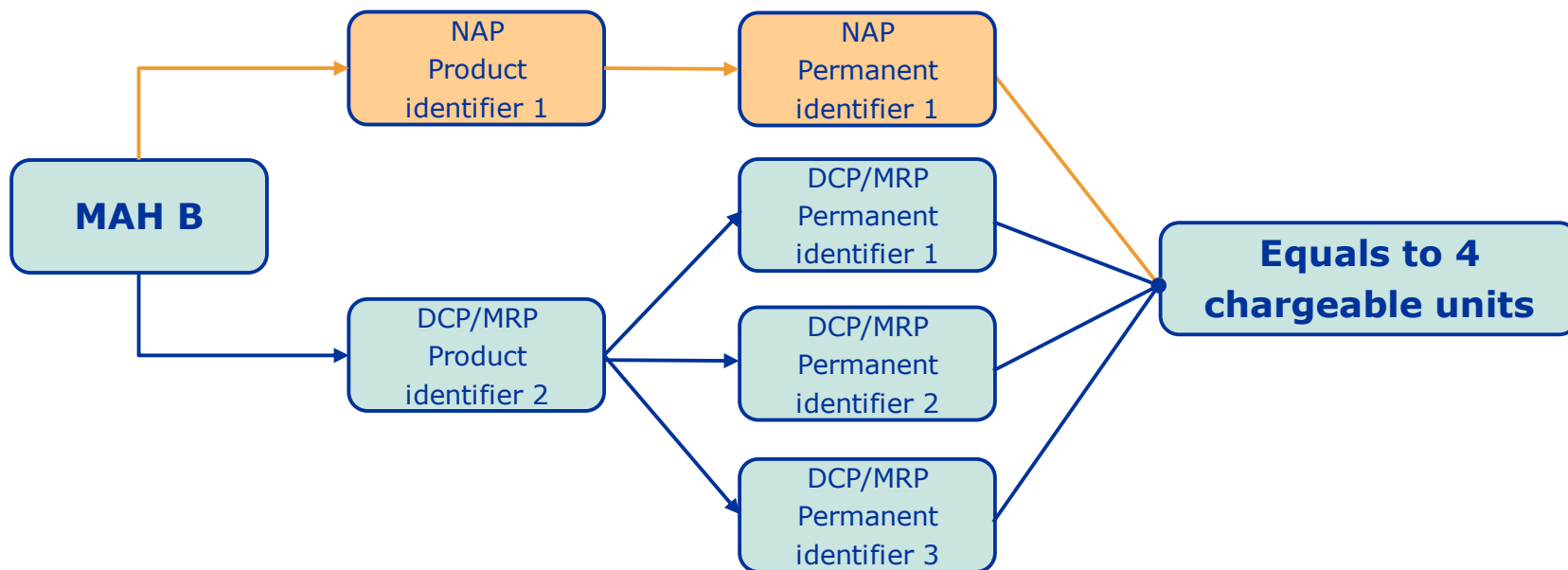
Use case 2

MAH A has **one** decentralised/mutual recognition (DCP/MRP) product, with **one** product identifier and **four** different permanent identifiers (e.g. same substance, pharmaceutical form, strength, **but authorised in four** Member States) = **4 chargeable units**



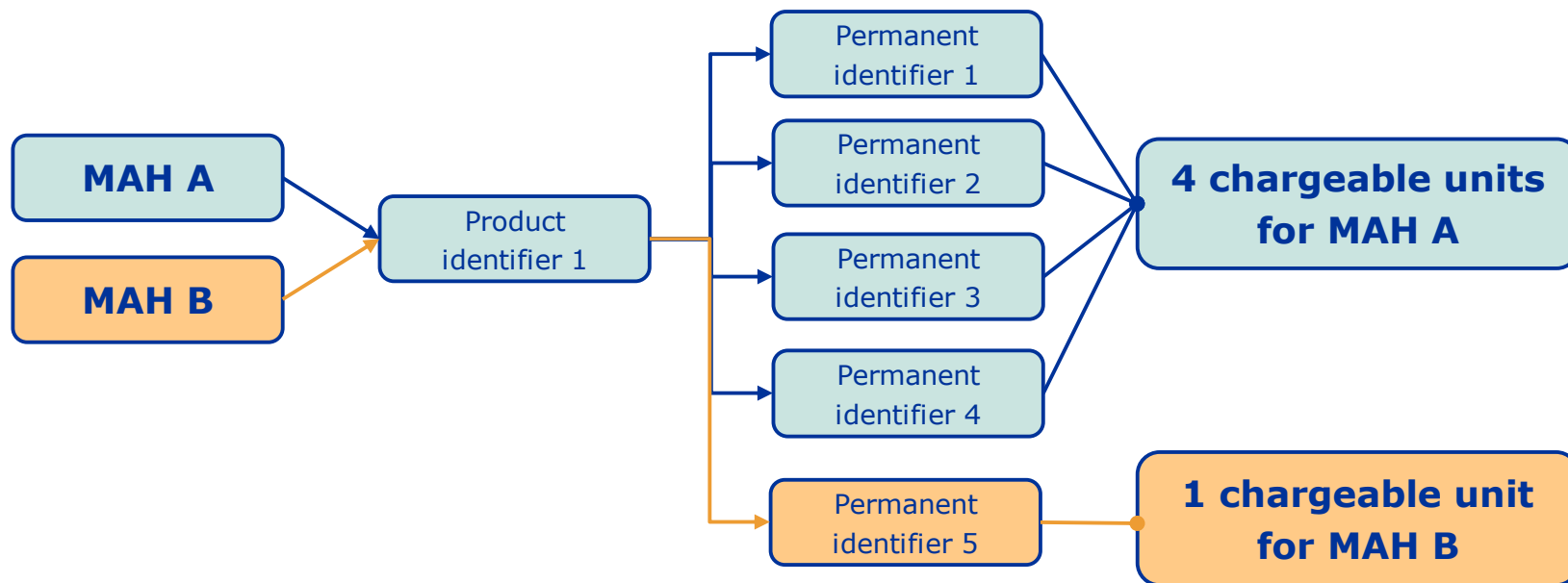
Use case 3

MAH B has **two products** (one NAP and one DCP/MRP authorised in 3 Member States) with same substance and pharmaceutical form, but different strengths = **4 chargeable units**

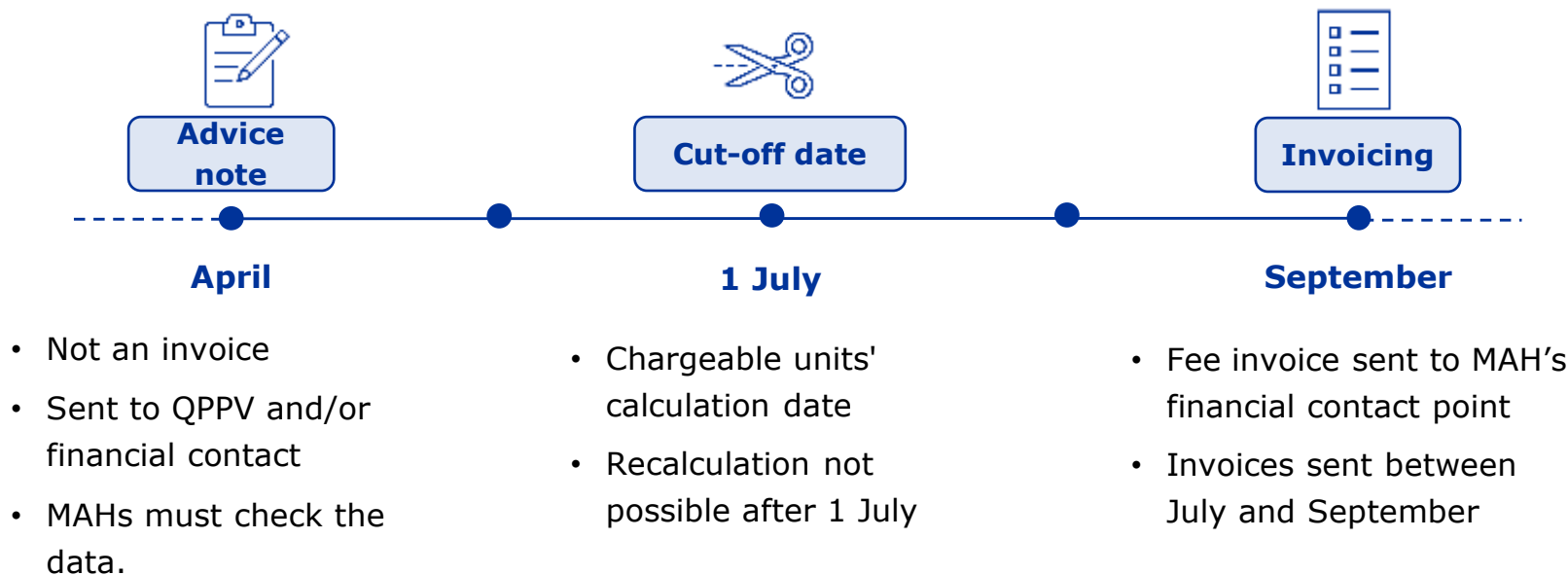


Use case 4

MAH A has the product authorised in **four** Member States and MAH B has the product authorised in another (**fifth**) Member State. The product has the **same substance, pharmaceutical form and strength**.



Agency's approach: **reuse existing methodology** for human pharmacovigilance annual fees.





Similar principle to the one used for the pharmacovigilance annual fees:

Multiple MAHs

- Amount payable by each MAH is calculated by dividing the total fee among MAHs, based on the number of chargeable units each MAH holds.

Advice note

- Not an invoice; sent to each MAH QPPV at the start of the procedure.
- MAHs have 30 calendar days to liaise with NCAs for any necessary change to the UPD data.

CAPs

- Centrally authorised products (CAPs) will be included in the fee calculation, ***if they are part of the procedure.***

Regulation (EU) 2024/568, Annex IV

Pre-submission activities

- A fee is charged with each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation.

Moving intended submission date

- A fee is charged when the intended submission date is moved by more than 60 days from the initial intended submission date.
- Can be applied multiple times, if multiple changes are made.

Re-examination of opinion

- A fee is charged when requesting the re-examination of an opinion.
- The fee is calculated at 30% of the initial fee paid.



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



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



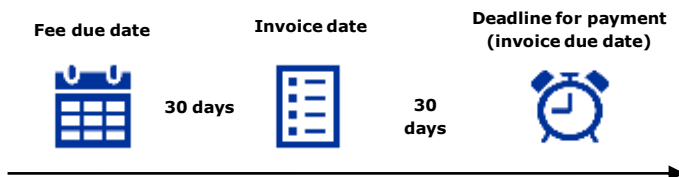
Raising a query

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

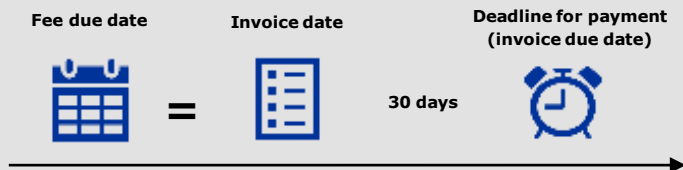
Specific provisions applicable only to services subject to **prepayment**
(Scientific Advice, Parallel Distribution and Certificates)

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

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

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**

Remittance advice

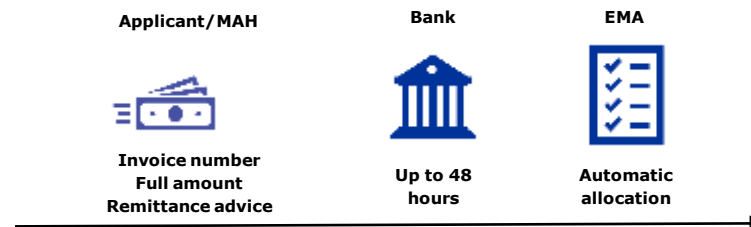
- Mandatory remittance advice in case multiple invoices are paid with one remittance (i.e. it requires manual allocation by EMA)
- In case of missing payment references, Agency contacts applicant financial contact point for confirmation of reason for payment (i.e. invoice number)

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

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

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



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

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.

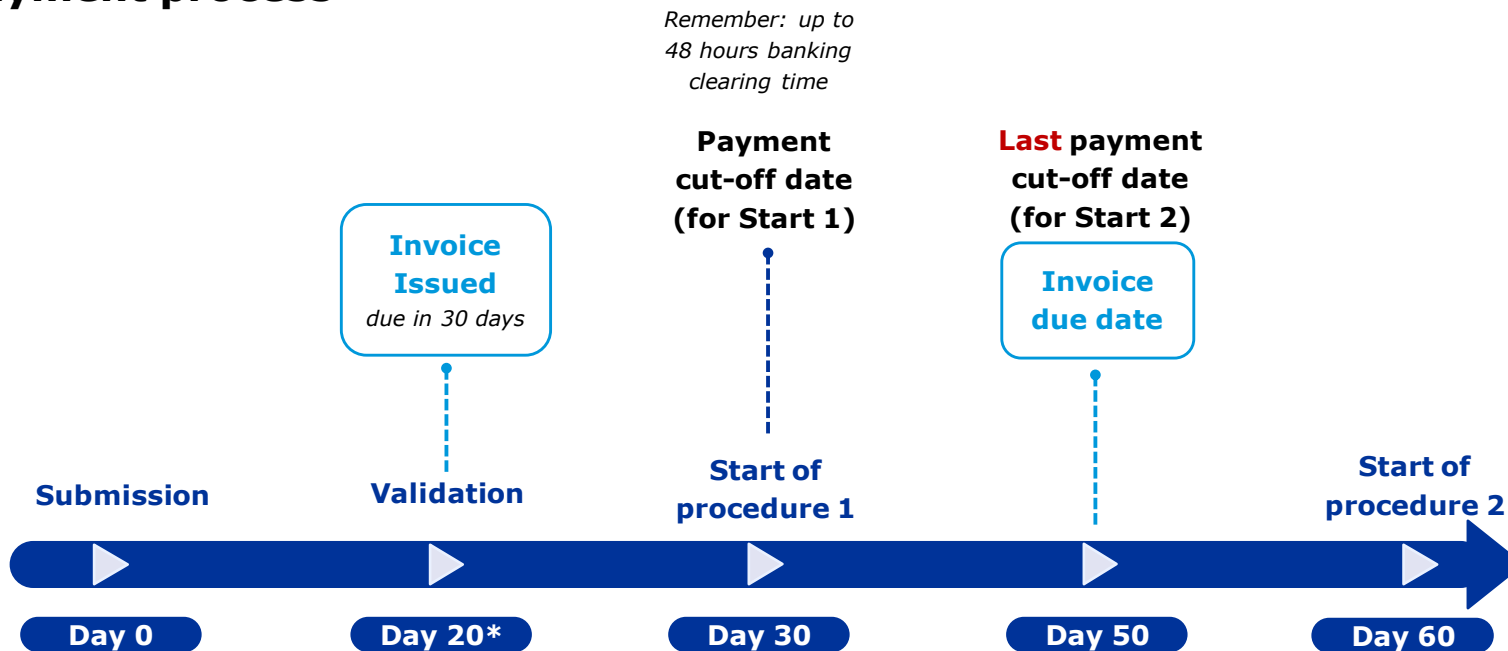
Item	Material Description	Customer Ref.	Amount	Cur.
	Application Number			
	Product Name			
	Site			
1	DETAILS OF TYPE OF PROCEDURE	REF / PO NUMBER provided by Applicant/ MAH	100,000,00	EUR
TOTAL			100,000,00	EUR

Payment by bank transfer only to: ABN-AMRO BANK N.V.
• IBAN NL384004037286506 • SWIFT ABNANL2A • Please quote our invoice number on the bank transfer

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Pre-payment process



**For illustration purposes*



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

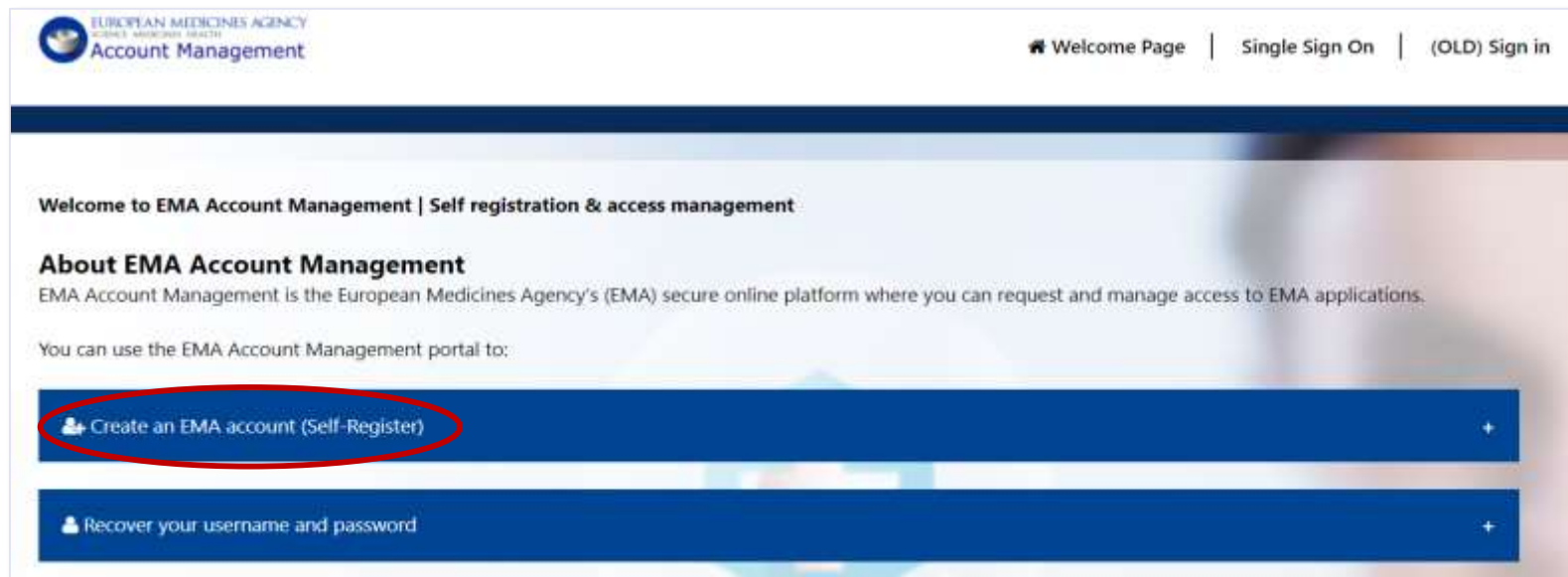
[How to pay](#) webpage content update



Closing and Q&A session

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](#).





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](#)



Public System Demo

12 December 2024



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