EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Administration and Corporate Management Division

How to pay fees and charges levied by EMA

Guidance to marketing authorization holders and applicants

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Disclaimer

The European Medicines Agency (EMA) provides guidance to applicants and marketing authorisation holders on how to pay fees levied by EMA.

The information provided in this guidance is for general information purposes only and is not legally binding. While the Agency strives to ensure accuracy, in case of discrepancy or conflict the applicable legislation takes precedence over the information in this guidance.

This content applies to human and veterinary medicines.

New Fee Regulation (applicable as of 1 January 2025)

The European Medicines Agency (EMA) charges fees for the services it provides. Regulation (EU) 2024/568 on **fees** and **charges payable to EMA** is applicable as of 1 January 2025[1]. It is also known as the "New Fee Regulation". A working arrangements document has been established in accordance with Article 8 of Regulation (EU) 2024/568 to facilitate the application of said regulation.

In line with the provisions of Article 71 of the Agency's financial regulation and with the entry into force of the New Fee Regulation, the following services will be provided only after the fee or charge has been paid in its entirety: **Scientific Advice, Certificates** of medicinal products and **Parallel Distribution**. These are also known as services subject to "**prepayment**".

1. Receiving an invoice from the Agency

1.1. Determination of applicable fee and due dates for fees and charges

The rules relating to the Agency's fees are governed by the fee regulation and its working arrangements, which stipulate, amongst other provisions, dates for the determination of the applicable fees and charges levels and due dates for fees and charges.

The **applicable fee level date determines the fee** or charge amount, the legal entity to be charged and the applicable fee incentive(s).

The **fee due date** is the date when **the fee** or charge **becomes payable** by the concerned legal entity.

When a fee or a charge becomes payable, i.e. at the **fee due date**, the Agency, based on the information established at the applicable fee level date, calculates the fee or charge and **issues an invoice** to the concerned legal entity, i.e. applicant or marketing authorisation holder.

Information such as billing address, purchase order number or similar reference available at the fee due date, are included in a record which generates an invoice, sent to the applicant or marketing authorisation holder.

The fee due date is distinct from the **deadline for payment** specified in the invoice issued by the Agency, as outlined in section 2.1.

[1] REGULATION (EU) 2024/568 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 7 February 2024 on fees and charges payable to the European Medicines Agency and amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95

1.2. Customer account number and designated contact point for financial matters

The **customer account number** is a unique reference number with the Agency for financial matters. It is quoted on the invoice and all the related financial correspondence received from the Agency. Applicants and marketing authorisation holders should quote their account number with the Agency on each procedural submission and in all correspondence related to financial matters.

The customer account number starts with 5* for Parallel Distributors and with 6* for all other legal entities. In some of the Agency's regulatory platforms (e.g. IRIS) and/or correspondence from EMA, this number can also be presented with leading zeros.

Applicants and marketing authorisation holders **being levied a fee or charge by EMA for the first time** should contact EMA's accounting team to request a 'new customer' form which will have to be filled in with the legal entity details, including the entity VAT number and the contact details of a designated person ("**financial contact point**") within the organisation, who will be responsible for financial matters such as receiving invoices, payment reminders, managing – if applicable - purchase order numbers or similar references, registering with the EMA Invoicing Portal, etc.

Upon creation of the legal entity in the Agency's financial system, the EMA's accounting team will communicate the customer account number to the requestor and the financial contact point, if different from the requestor.

1.3. Legal address, billing address and Value Added Tax (VAT) number

EMA issues invoices to the applicant or marketing authorisation holder's **legal address** held on the Agency's file at the applicable fee level date, referred to in section 1.1.

Applicants and marketing authorisation holders requiring their invoices to be issued to a different address other than the legal address should contact EMA's accounting team to request the addition of such address, also known as "**billing address**", to their record. Only one billing address can be associated to one legal entity. As such the billing address will be applicable to all invoices issued to the concerned applicant or marketing authorisation holder, regardless of the type of application or service the fee or charge relates to.

Applicants and marketing authorisation holders requiring their **VAT number** on their invoice should provide such number to accountsreceivable@ema.europa.eu.

The invoice is **dispatched** by EMA in PDF format, from its acccountsreceivable@ema.europa.eu email address, to the email address of the financial contact point. Alternatively, the invoice can be **downloaded from the EMA Invoicing Portal**, subject to prior registration of the financial contact point with said portal. Please refer to section 1.7 for further information on the EMA Invoicing Portal. On request, the Agency can also dispatch hard copies of invoices, by traditional post.

Applicants and marketing authorisation holders are reminded of their responsibility for the **accuracy** of the information held on the Agency's file and encouraged to verify periodically their details with the EMA's accounting team. In addition, the Agency recommends its email address is 'whitelisted' to avoid invoices being blocked or placed in a spam folder instead of the financial contact point's inbox.

Changes to the billing address and financial contact point email's address should be communicated in writing to accountsreceivable@ema.europa.eu at the earliest convenience and prior to the fee or charge becoming due.

Please refer to section 3.2 for the Agency's procedures on dealing with disagreement on fees and charges and other queries on invoices.

1.4. Numbering and content of EMA invoices

EMA's **invoice numbering** starts with:

- 7* for marketing authorisation fees and charges;
- 8* for pharmacovigilance fees;
- 9* for marketing authorisation fees and charges which are subject to prepayment.

In some of the Agency's regulatory platforms (e.g. IRIS) and/or correspondence from EMA, the invoice number can also be presented with leading zeros.

Invoices for **marketing-authorisation fees** and charges contain:

- details of the product and type of procedures involved;
- the fee amount and financial information.

Invoices for **pharmacovigilance fees** contain:

- details of the procedure;
- the total number of chargeable units attributable to the marketing authorisation holder;
- information on any fee exemptions or reductions applicable to the pharmacovigilance fee;
- the fee amount and financial information.

For Scientific Advice and Parallel Distribution services, once an invoice is issued, the financial information screen of the Agency's IRIS regulatory platform will be updated with the invoice number, its amount and the invoice due date, confirming that the invoice has been issued. For Certificates, an email notification will be sent to the requestor confirming that an invoice has been issued.

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 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 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000 **Website** www.ema.europa.eu

An agency of the European Union

Figure 1 - Example of EMA invoice

1.5. Purchase order number or similar reference

Applicants and marketing authorisation holders operating a "**no Purchase Order - no Pay**" policy are strongly encouraged to add EMA to their purchase order exemption list.

Alternatively, applicants and marketing authorisation holders can issue a **standing (blanket) purchase order** covering all marketing authorisation and/or pharmacovigilance fees levied by the Agency for a given period and provide such reference to accountsreceivable@ema.europa.eu.

The reference can also be provided when submitting the application via the Agency's regulatory platforms (e.g. IRIS) by using the **dedicated field** in the **submission form**, where applicable.

References communicated to EMA in ways other than the ones specified above will be discarded by the Agency.

Applicants and marketing authorisation holders are reminded of their responsibility for ensuring the **validity** of such **purchase order numbers** provided to EMA and, in the case of standing (blanket) purchase orders, are encouraged to confirm periodically the validity of such references to the EMA's accounting team.

Please refer to section 3.2 for the Agency's procedures on dealing with disagreement on fees and charges and other queries.

1.6. VAT provisions applicable to EMA

The European Medicines Agency has been established in accordance with Regulation (EC) 726/2004 of the European Parliament and the Council (published in the OJ L136, 30.4.2004), and pursuant to Article 74 of the said Regulation, the **Protocol on the Privileges and Immunities of the European Union** (Protocol VII of the TFEU) is applicable to the Agency.

Article 3 of Protocol VII establishes that "The Union, its assets, revenues and other property shall be exempt from all direct taxes", and therefore by virtue of the above provisions, the Agency is not subject to the jurisdiction of the NL Tax Authority and is exempt from direct taxes within the EU, including withholding tax. Consequently, **EMA does not have a VAT number**.

1.7. EMA Invoicing Portal

The Agency has implemented an on-line invoicing portal service, also known as **"EMA Invoicing Portal"**, enabling applicants and marketing authorisation holders to:

- get instant access to their account with EMA;
- view and print-out invoices;
- view their detailed chargeable units line listing for pharmacovigilance fees;
- raise queries on invoices;
- search and download copies of archived invoices;
- view payments made;
- manage billing addresses.

Financial contact points are encouraged to **register with the EMA Invoicing Portal**. To register please select 'Register now' on the portal log-in page https://fees.ema.europa.eu/bd/public/zindex.jsp and follow the instructions on screen.

Applicants and marketing authorisation holders **being levied a fee by EMA for the first time** will only be able to register for the EMA Invoicing Portal upon receipt of their first invoice.

To register with the EMA invoicing Portal applicants and marketing authorisation holders will be required to fill in the user registration form and provide us with the following information:

- Customer account number: this is the unique reference number assigned by the Agency to the legal entity for which a financial contact point is registering as a portal user. The customer account number can be found on the invoice;
- Company name: this is the name of the legal entity for which a financial contact point is registering as a portal user. The name of the legal entity entered in the registration form should be exactly as stated on the invoice;
- User first name: the financial contact point first name;
- User surname: the financial contact point surname;
- User email address: the email address to which the applicant or marketing authorisation holder would like the email notification of invoice availability to be sent by the Agency;
- Invoice number: the number of the last invoice issued by the Agency to the legal entity for which a financial contact point is registering as a portal user.

2. Paying an invoice to the Agency

2.1. Deadline for payment of an invoice

Payments shall be made only after having received an invoice from the Agency. Invoices are issued at the fee due date, as outlined in section 1.1.

The deadline for payment is the **payable date** indicated on the invoice, also known as "**invoice due date**", i.e. 30 calendar days from the date of the invoice.

Ten calendar days before the invoice due date, EMA sends a pre-reminder to the financial contact point informing them that the deadline for payment is approaching.

With respect to **Scientific Advice** services, the Agency recommends that the invoice is paid as soon as possible upon receipt, so that the payment is received in the Agency's bank account before the intended start date of the procedure. If the payment is received after said date but before the invoice due date, the request will be evaluated in the following start date of procedure, i.e. the following month. Please refer to the Scientific Advice and Protocol Assistance page for submission deadlines, start of procedure dates and related cut-off dates for payment.

Any payment received prior to an invoice being issued by the Agency will result in the amount remaining unallocated and therefore in a credit balance on the applicant or marketing authorisation holder's account, which will be handled by EMA in line with the procedure outlined in section 2.5, Credit balances and refund process.

Specific provisions apply to fees for a marketing authorisation of a medicinal product which have been **deferred** pursuant to the rules applicable to micro, small and medium-size enterprises (**SMEs**)[2]. Said fees must be paid within 45 calendar days of the date of the notification of the final decision on the

[2] Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises

marketing authorisation, or within 45 calendar days of the date of the notification of withdrawal of the application.

2.2. Agency's bank account details, bank charges and remittance advice

The Agency's invoices must be paid in **euro,** net of all bank charges, withholding taxes and any other deductions, by means of a **transfer to the bank account of the Agency**:

ABN AMRO Bank N.V.
IBAN: NL33 ABNA 0837 2865 06
SWIFT: ABNANL2A

Typically, SEPA[3] transfers are processed within a 24-hour period i.e. up to one business (or banking[4]) day, from the moment they are initiated by the payer to the moment they are received on the beneficiary's bank account.

Non-SEPA transfers may take longer, generally around one to five business days, often due to the processing time of the intermediary or 'holding' bank and therefore can also carry higher charges.

Bank charges shall always be **borne by the payer**[5]. Payers processing non-SEPA transfers should select the option 'OUR', as opposed to 'SHA' (i.e. shared bank charges) or 'BEN' (i.e. bank charges covered by the beneficiary) in the payment instruction to the bank, for the Agency to receive the entire amount in relation to the corresponding invoice.

The Agency strongly encourages payers to make their payments from a bank account **within SEPA** to avoid additional bank charges and longer processing times.

When processing a payment, applicants and marketing authorisation holders **are required** to send to the EMA's accounting team a **remittance advice** indicating invoice number(s), amount(s) and date of payment(s).

2.3. Allocation of payments received in the Agency's bank account

Every business day, the Agency receives from its bank the statement of payments received on the previous banking day and performs an **automatic allocation** of said payments against the corresponding invoices. For example, payments received on EMA's bank account on Friday are processed by EMA on Monday.

The allocation process consists in matching the amount paid and the invoice number quoted by the payer in the payment reference field of the bank transfer against the amount and number of the corresponding (open) invoice on any given customer account.

In general, and more particularly for services subject to prepayment, for as many payments as possible to be allocated automatically to the corresponding invoices, with limited or no manual intervention by EMA, **payers shall therefore ensure that**:

- payments are made only **after having received an invoice** from the Agency;
- where possible, **one single payment** is processed for each individual invoice. This is very important in the case of payments related to requests for Scientific Advice;

[3] Single European Payments Area
[4] A banking day is any day on which banks are open to the public and are generally carrying on their normal banking functions. A banking day is generally any day except Saturday, Sundays and legal holidays.
[5] The applicant or marketing or, generally, the entity making the payment to the Agency.

- the **EMA nine-digit invoice number** is accurately quoted in the payment reference field. In case of multiple invoices being paid within the same bank transfer, payers are requested to duly quote in the payment reference field all the relevant invoices' numbers;
- the **amount** to be received by EMA is corresponding exactly to the amount of the invoice(s), with no deductions for bank charges, as outlined in section 2.2.

If the automatic allocation of payment is successful, the financial information screen of the Agency's IRIS regulatory platform for Scientific Advice and Parallel Distribution services will be updated, confirming that the payment has been received and successfully allocated. For Certificates, an email notification will be sent to the requestor confirming that the payment has been received and successfully allocated.

If the automatic allocation of payment fails, for example because of unclear payment reference; and/or missing remittance advice; and/or unmatching amounts, the **EMA's accounting team will contact the financial contact point** requesting a confirmation of the payment reason i.e. the invoice number. In this case, manual intervention will be required and it might take longer for EMA to confirm that the payment has been received and successfully allocated.

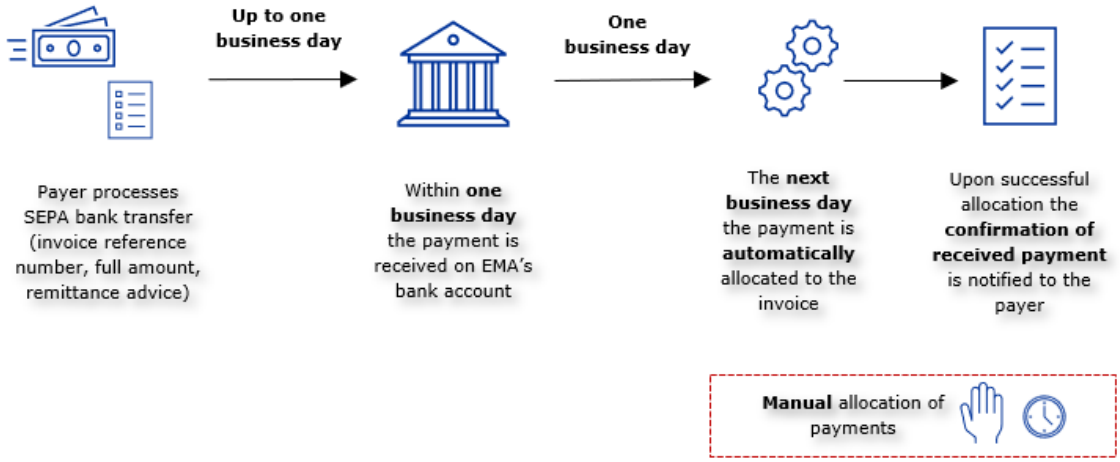

Figure 2 – Processing time of bank transfer and allocation of payments

2.4. Late payment or non-payment of an invoice

The Agency operates a **dunning system** which foresees regular communication with applicants and marketing authorisation holders to collect payments that are due or past due.

Ten calendar days before the invoice due date, EMA sends a pre-reminder to the financial contact point informing them that the deadline for payment is approaching.

For **services not subject to prepayment**, if the payment is not received by the deadline for payment i.e. 30 calendar days from the date of the invoice, the Agency will pursue collection by sending additional payment reminders by email, letter and phone. The Agency reserves also the right to apply the provisions of its financial regulation and the fee regulation and:

- charge interest at the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Communities, in

force on the first calendar day of the month in which the due date falls increased by three and a half percentage points as provided in Regulation (EU, Euratom) 2018/1046 and EMA's Financial Regulation, and/or

- refuse to provide the requested services or to suspend all the services and procedures under way; and/or
- effect recovery by enforcement of any guarantee lodged in advance; and/or
- effect recovery by legal action.

For **services subject to prepayment**, if the payment is not received by the deadline for payment i.e. 30 calendar days from the date of the invoice, both application and invoice will be cancelled, the services will not be provided and, for Scientific Advice, an administrative charge will apply.

2.5. Credit balances and refund process

A credit balance refers to an amount that EMA owes to an applicant or marketing authorisation holder because of an **overpayment** made to the Agency.

An overpayment may originate from a credit note for correction on a fee or charge being issued by EMA to the applicant or marketing authorisation holder, but not yet refunded; from the applicant or marketing authorisation holder having paid an invoice for more than its amount; from a payment received prior to an invoice being issued by EMA or from a payment received after an invoice for services subject to prepayment has been cancelled, as outlined in section 2.4.

In line with its accounting procedures, each month EMA sends a statement to the financial contact point informing that there are credits on their account.

Credit balances are **automatically refunded** to the payer, unless the Agency retains the credit because the applicant or marketing authorisation holder has invoices on account which are past due.

The applicant or marketing authorisation holder may also request to retain the credit on account to be offset against future invoices. Please note, however, that this option is **not applicable** to invoices for services subject to **prepayment**, i.e. Scientific Advice, Certificates and Parallel Distribution.

In compliance with the EMA anti-fraud strategy, refunds are sent by default to the bank account from where the original payment was made. Applicants and marketing authorisation holders requiring a refund to be sent to a different bank account (e.g. when the original bank account is no longer open) will be requested to provide additional supporting documentation such as proof of closure of original bank account and copy of bank statement header with new bank details. This process will also be subject to EMA 'call back' verifications.

3. Raising a query on an invoice

3.1. How to raise a query on an invoice

Any query arising on an invoice must be notified to the Agency **as soon as possible** upon receipt of the invoice.

As outlined in section 1.7, EMA operates an Invoicing Portal through which applicants and marketing authorisation holders can raise queries on their invoices. Raising a query on an invoice via the EMA Invoicing Portal will ensure said query is redirected to the responsible department for processing in a timely manner.

Applicants and marketing authorisation holders sending a query on an invoice to any other Agency's email address will be requested to resubmit their query via the EMA Invoicing Portal.

Queries on invoices which were already paid shall be submitted to the Agency via the dedicated EMA fees query form.

3.2. Agency's procedure for handling queries on invoices

Queries on invoices will be treated by the Agency in accordance with the procedure set forth below:

- **Disagreement on the fees and charges** will not suspend the payment period for said invoice and, therefore, the invoice shall still be paid by its due date. Should the disagreement lead to a correction of the contested invoice, any amount overpaid in connection with said invoice shall be reimbursed by the Agency or offset against a future invoice of the same entity, in agreement with the applicant or marketing authorisation holder in accordance with the procedure outlined in section 2.5 Credit balances and refund process.
- Rejections of EMA invoices by the applicant or marketing authorisation holder on the grounds that a **purchase order number** or similar reference is not quoted on the invoice or is no longer valid, will not be accepted. The use of the purchase order system is an internal control process of the applicant, it is not binding on the Agency and it cannot be used as reason to withhold the payment of the Agency's fees.
- Rejections of EMA invoices by the applicant or marketing authorisation holder on the grounds that a **billing address** is not valid will not be accepted unless the new billing address was communicated and received by the Agency prior to the fee or charge becoming due (section 1.1). The Agency will not process retrospectively any change to the billing address for invoices which have already been issued.
- Disagreement on interest charged on an invoice having been paid late because the **email address** of the financial contact point, where the invoice was dispatched, became invalid, will not be accepted, unless an alternative email address was communicated and received by the Agency prior to the fee or charge becoming due (section 1.1).

Please refer to section 2.4 for the Agency's procedures on dealing with late-payment or non-payment of an invoice.

4. Contact point

For **general queries on fees** such as composition and types of fee, fee prices, fee codes, application numbers and procedures, please fill in and submit the EMA fees query form.

For questions on **receiving, paying and raising a query on an invoice** that are not covered in this guidance, please contact the EMA's accounting team at accountsreceivable@ema.europa.eu.

EMA advises applicants and marketing authorisation holders to be vigilant about phishing attempts involving emails appearing to be from EMA. If in doubt, please contact EMA's accounting team at accountsreceivable@ema.europa.eu to verify the authenticity of any EMA correspondence.