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Administration and Corporate Management Division

# SEPA Direct Debit Business-to-Business (B2B)

Guidance for applicants and marketing authorisation holders

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# Disclaimer

The European Medicines Agency ('EMA' or 'the Agency') provides guidance to applicants and marketing authorisations holders on how to pay its fees by SEPA Direct Debit under the Business-to-Business (B2B) scheme.

The **SEPA Direct Debit B2B** is a payment scheme under the Single Euro Payments Area framework that allows creditors to collect euro-denominated payments from business debtors[1] based on a signed mandate, where the debtor must be a non-consumer entity and the bank of the debtor performs mandatory mandate verification before executing the debit.

This guidance is based on the **EPC SEPA Direct Debit Business to Business Scheme Rulebook and related implementation guidance issued by the European Payments Council**[2]. It is provided for general informational purposes only and does not constitute legal, regulatory, or banking advice. In case of divergence, the official EPC rulebook and the debtor/creditor banks' implementation guidelines prevail.

**The SEPA Direct Debit B2B payment method is currently available ONLY for payment of invoices related to services subject to prepayment (Scientific Advice, Certificates and Parallel Distribution).**

This guidance may be subject to further refinement based on feedback and operational experience.

# 1. Setting up SEPA Direct Debit B2B

## *1.1. Agreement to use SEPA Direct Debit B2B*

To set up SEPA Direct Debit B2B, the applicant or marketing authorisation holder ('payer' or 'debtor' or 'legal entity') must have a customer account with EMA and must complete and sign a SEPA Direct Debit B2B mandate **authorising** EMA (the creditor) to collect amounts due by direct debit on a recurring basis.

Applicants and marketing authorisation holders interested in subscribing to this payment method should request the SEPA Direct Debit B2B mandate form by contacting the EMA's accounts team at accountsreceivable@ema.europa.eu.

## *1.2. How to fill in the SEPA Direct Debit B2B mandate*

This section provides guidance on how to complete each field of the SEPA Direct Debit B2B mandate and explains their purpose.

Mandate Reference

- This field is for **EMA use only**.
- It will be populated by the Agency with a unique mandate reference once the mandate is processed.
- The **unique mandate reference** will be communicated by the Agency to the payer.
- No action is required from the payer.

[1] In the context of this definition EMA is the creditor and the applicant/marketing authorization holder is the debtor
[2] Rulebook and implementation guidelines to implement the SDD B2B scheme | European Payments Council

Creditor Details

- These fields are **pre-filled by EMA** and **must not be modified**.
- They include:
    - EMA's legal details
    - The Creditor Identifier, which is the unique SEPA identifier assigned by EMA's bank
- These details identify EMA as the entity **authorised** to initiate direct debit collections.

Debtor (Payer) Details

- This section must be **fully completed by the applicant/marketing authorisation holder**.
- The information provided must be **accurate and consistent** with bank records, as it will be verified by the payer's bank.

Customer Account Number

- This is the unique identifier assigned by EMA to the applicant/marketing authorisation holder.
- It is referenced in EMA invoices.
- It is important to ensure that:
    - The number corresponds to the correct legal entity, and
    - The same entity is reflected in the mandate and bank records

This ensures proper allocation of payments to the correct customer account.

Bank Account Details (IBAN/BIC and Account Holder Name)

- The bank account holder name must match exactly the name registered with the payer's bank
- The IBAN and BIC must correspond to a business (non-consumer) bank account
- Discrepancies may lead to:
    - Rejection of the mandate by the bank
    - Failed or returned transactions

Accuracy in this section is critical for successful mandate registration and payment execution.

Type of Payment

- This field is pre-selected as **'Recurrent'**
- It indicates that the mandate authorises EMA to collect payments on an ongoing basis (not just a one-off transaction)

One mandate per legal entity (even with shared bank accounts)

When several applicants/marketing authorisation holders within the same group share a single bank account, **one SEPA Direct Debit B2B mandate** must be issued **for each legal entity within the group having a customer account with EMA**, regardless of shared banking arrangements, even if the IBAN and authorized signatories are identical.

This is because a SEPA Direct Debit B2B mandate is legally linked not only to the bank account, but also to the exact legal identity of the debtor. Banks validate B2B mandates against the debtor's registered company name, and not solely against the IBAN.

### 1.3. Signature of the mandate

The mandate must be signed by an authorised representative of the payer. The signatory must have the legal authority to bind the company and approve direct debit transactions on its behalf.

Electronic signatures are accepted only where permitted by the payer's bank and provided that they allow verification of the signer's identity and the integrity of the document.

### 1.4. Returning the mandate to the Agency

The payer shall return the signed SEPA Direct Debit B2B mandate to EMA either:

- in paper form, in the case of a handwritten (wet) signature, to the Agency postal address; or
- as a scanned PDF sent via email[3] to accountsreceivable@ema.europa.eu.

EMA retains a copy of the signed mandate for the duration of its validity, in accordance with applicable SEPA rules.

Upon receipt of the signed mandate from the payer, the Agency will activate the mandate, assign a unique mandate reference and communicate it to the payer.

### 1.5. Registration of the mandate with the payer's bank

The payer is responsible for ensuring that the signed SEPA Direct Debit B2B mandate, including the unique mandate reference, is registered with its bank before the first collection takes place.

The registration process for SEPA Direct Debit B2B mandates is not fully standardised across Europe. While the EPC scheme rules require the payer's bank to verify the mandate before processing collections, the operational registration method is determined by each bank and may, for example, involve registration through an online banking portal or submission of the signed mandate in paper or PDF format.

### 1.6. Transition from bank transfer to SEPA Direct Debit B2B method of payment

EMA cannot initiate SEPA Direct Debit B2B collections until the mandate has been accepted by the payer's bank.

**The payer is therefore requested to inform EMA once the mandate registration process with its bank has been completed, so that the date of the first SEPA Direct Debit B2B collection can be agreed with the Agency.**

Applicants and/or marketing authorisation holders should also ensure that their regulatory and financial teams are appropriately aligned internally, including in relation to invoices approval processes, to support a smooth transition between payment methods.

To help ensure a smooth setup process, please refer to the checklist provided in Section 5, Annex.

[3] Secure email transmission is recommended (e.g. DocuSign)

# 2. Collection process

Please note that the SEPA Direct Debit B2B payment method is currently available **ONLY** for payment of invoices related to services subject to prepayment, namely **Scientific Advice, Certificates and Parallel Distribution.**

## *2.1. Selective use of SEPA Direct Debit B2B*

By signing a SEPA Direct Debit B2B mandate, the payer authorises EMA to collect payments by direct debit. This does not mean that all invoices must be paid using this method of payment. Payers may choose to use SEPA Direct Debit B2B only for certain services, while other invoices can continue to be paid by bank transfer.

When returning the mandate to EMA, the payer must also inform EMA for which of the three above-mentioned services it authorises EMA to collect payments by direct debit.

These arrangements are based on mutual agreement between EMA and the payer and are not shown on the mandate itself.

## *2.2. Pre-notification of collection*

In accordance with the SEPA Direct Debit B2B scheme, EMA shall provide 14 days advance notice of collections unless otherwise agreed with the payer.

SEPA Direct Debit B2B payment method is currently available ONLY for payment of invoices related to services subject to prepayment, by signing a mandate the payer expressly agrees that **the invoice**:

- **constitutes** the pre-notification for the SEPA Direct Debit B2B collection; and
- **informs** the payer that EMA may submit the direct debit collection instruction to its bank on the business day following the invoice date.

These arrangements are based on mutual agreement between EMA and the payer and are not shown on the mandate itself.

## *2.3. Payment finality under the SEPA Direct Debit B2B scheme*

Under the SEPA Direct Debit B2B scheme, a payment is not considered final immediately after the account of the payer has been debited.

A direct debit transaction may be 'returned' by the payer's bank to the creditor's bank, within three business days following the debit date (i.e. the day the payment is executed) for specific scheme-defined reasons[4].

In this context, 'returned' means that the payer's bank sends the transaction back (i.e. reverse) through the SEPA banking system, resulting in the cancellation of the payment and the reversal of the funds, which are not ultimately received by EMA.

Please note that the **payer** themselves **cannot initiate** a return in the SEPA Direct Debit B2B scheme. The return can only be initiated by the payer's bank.

[4] Scheme-defined reasons, each associated with a standard return reason code are for example: the mandate is not registered with the payer's bank; the mandate details do not match what is registered; the account is closed or blocked; there are insufficient funds (depending on bank policy) or a technical or processing error is detected

Once the 'three-business day return period' has elapsed, the right to return the transaction expires and the direct debit transaction i.e. payment becomes final and irrevocable.

Accordingly, EMA will consider the payment as received only once this period has expired and the transaction has become final and irrevocable.

It is important to ensure the successful execution of SEPA Direct Debit B2B collections and to minimise returned transactions, as such returns may affect the processing of the request and consequently delay or prevent the provision of the service.

Where a transaction is returned or cannot be successfully processed, EMA may be unable to proceed with the related request or provide the requested service until payment has been successfully received and has become final and irrevocable.

Applicants and marketing authorisation holders are therefore strongly encouraged to ensure that:

- a valid SEPA Direct Debit B2B mandate is in place;
- the mandate has been correctly registered with the payer's bank;
- sufficient funds are available on the account;
- and the account details provided to EMA remain accurate and up to date.

### 2.3.1. Definition of 'three-business day return period'

The 'three-business day return period' means three TARGET[5] business days after the debit date, not three calendar days and not necessarily three local working days.

For the purposes of SEPA Direct Debit B2B processing, business days are TARGET business days used by the SEPA payment system. SEPA Direct Debit clearing only occurs on TARGET business days.

This means that weekends do not count and extends the three-business day return period and certain Eurosystem holidays do not count, even if some national banks are open locally[6].

Therefore, EMA reserves the right to adjust its SEPA Direct Debit B2B collection submission scheduling and service release timing in accordance with both the annual TARGET operating calendar and the EMA holiday calendar.

## *2.4. Standard collection process flow with indicative timelines*

The indicative timeline below illustrates the SEPA Direct Debit B2B standard collection process for services subject to prepayment. It assumes that a SEPA Direct Debit B2B mandate has been put in place, registered and validated by the payer's bank.

| Day | **Event** | **Status** |
|---|---|---|
| Day 1 | Applicant submits request/application | Request received by EMA |
| Day 1 | EMA issues invoice | Invoice serves as pre-notification |
| Day 2 | EMA submits SEPA Direct Debit B2B collection instruction to its bank | Collection process initiated |

[5] A TARGET business day is a day on which the TARGET system (Trans-European Automated Real-time Gross Settlement Express Transfer system or T2) is open for settlement.
[6] The TARGET system is normally closed on Saturdays, Sundays, New Year's Day (1 Jan), Good Friday, Easter Monday, Labour Day (1 May), Christmas Day (25 Dec), Boxing Day (26 Dec).

| Day | Event | Status |
|---|---|---|
| Day 3 | Payer's account debited (debit date) | Funds provisionally credited to EMA's bank account<br><br>Transaction i.e. payment not yet final and irrevocable |
| Day 3-6 | Three-business day return period under SEPA Direct Debit B2B scheme | Transaction i.e. payment not yet final and irrevocable<br><br>The payer's bank may still return the transaction for scheme-defined reasons |
| Day 7 | Expiry of return period | Payment considered final and irrevocable |
| Day 8 | EMA can proceed with the provision of the service | Prepayment condition fulfilled |

## *2.5. Returned transactions and implications for service requests*

The following section addresses returned SEPA Direct Debit B2B transactions and the related implications for requests and service provision.

| Day | Event | Status |
|---|---|---|
| Day 1 | Applicant submits request/application | Request received by EMA |
| Day 1 | EMA issues invoice | Invoice serves as pre-notification |
| Day 2 | EMA submits SEPA Direct Debit B2B collection instruction to its bank | Collection process initiated |
| Day 3 | Payer's account debited (debit date) | Funds provisionally credited to EMA's bank account |
| Day 3-6 | Three-business day return period under SEPA Direct Debit B2B scheme | Transaction i.e. payment not yet final and irrevocable<br><br>The payer's bank may still return the transaction for scheme-defined reasons |
| Day 5 *(example)* | The payer's bank detects a valid scheme-defined return reason and returns the transaction to EMA | Collection reversed and funds are debited back from EMA |
| Day 7 | Expiry of return period: EMA receives return notification from its bank and identifies the return reason | Prepayment condition <u>not</u> fulfilled |
| Day 7 onwards | EMA contacts the applicant/payer | New payment and corrective action required |
| Day 7 onwards | SEPA Direct Debit B2B collection suspended until corrective action is in place | Alternative payment to be processed (i.e. bank transfer) |

| Day | **Event** | **Status** |
|---|---|---|
| Day 7 onwards | Applicant pays by bank transfer by invoice due date | Payment becomes final |
| Following successful new payment | EMA can proceed with the provision of the service | Prepayment condition fulfilled |
| Anytime | Applicant informs EMA corrective action has been put in place | SEPA Direct Debit B2B restored |

If the alternative payment is not received by the invoice due date, i.e. 30 calendar days from the date of the invoice, the existing cancellation process shall apply.

| **Day** | **Event** | **Status** |
|---|---|---|
| Day 30 | No new payment received | Prepayment condition not fulfilled |
| On or just after Day 30 | Invoice and application cancelled | Service not provided and administrative charge levied, if applicable |

## *2.6. Withdrawal of requests/applications*

Applicants and/or marketing authorisation holders who have set up SEPA Direct Debit B2B should be aware of the implications of withdrawals or cancellations, as **EMA will not be able to stop the collection once the direct debit instruction has been submitted to the bank for processing**.

In line with the EMA guidance on withdrawal of requests for **certificates** of medicinal products (section 6.2.4) and for **parallel distribution** applications (section 6.3.3) once a request has been submitted and the relevant fees have been paid in full, changes or cancellations or withdrawals are not accepted.

With respect to **Scientific Advice** requests, in line with the guidance on withdrawals (section 1.4) the Agency will apply the standard process:

a. if the request is withdrawn within 24 hours from your submission in the IRIS portal, the withdrawal will be free of charge. The Agency will not be able to stop the collection once the direct debit instruction has been submitted to the bank for processing, however the fee, where collected, will be returned in full.

b. if the request is withdrawn after 24 hours from its submission and prior to the completion of the administrative validation, an administrative charge will apply. The Agency will not be able to stop the collection once the direct debit instruction has been submitted to the bank for processing, however the fee, where collected, will be returned after deduction of the administrative charge. For micro, small or medium sized enterprises, the administrative charge shall be waived.

c. If the request is withdrawn after the administrative validation, the Agency will retain the full fee.

# 3. Other matters

## 3.1. Handling duplicate payments

The Agency cannot maintain two payment methods for the **same payer** in relation to the **same selected service** (and related invoice).

Where an applicant and/or marketing authorisation holder has designated SEPA Direct Debit B2B as the primary payment method for the selected services, any payment received for the same service (and related invoice) after that invoice has already been collected via SEPA Direct Debit B2B will be considered a **duplicate payment** and will be returned to the payer's bank account.

Payments by standard bank transfer are accepted only where a SEPA Direct Debit B2B collection has been unsuccessful due to a returned transaction and the SEPA Direct Debit B2B collection is suspended pending implementation of a corrective action, as described in Section 2.5.

The Agency recommends applicants and/or marketing authorisation holders to ensure that their regulatory and financial teams are appropriately aligned internally, including in relation to invoices approval processes, to support a smooth transition between payment methods and the efficient management of the SEPA Direct Debit B2B process thereafter.

## 3.2. Amending or cancelling the mandate by the debtor

Applicants and/or marketing authorisation holders wishing to amend or cancel their SEPA Direct Debit B2B mandate are requested to contact accountsreceivable@ema.europa.eu, quoting *'Amendment/cancellation of SEPA Direct Debit B2B'* and the customer account number in the email subject.

## 3.3. Termination of the mandate by the Agency (creditor)

In the event of repeated failed SEPA Direct Debit B2B collection attempts and subsequent returns, EMA may request termination of the mandate with the payer and proceed to recover any related charges from the payer.

## 3.4. Bank charges

The Agency offers the SEPA Direct Debit B2B service free of charge. However, in accordance with Article 7 of 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, the Agency reserves the right to recover from the payer and by SEPA Direct Debit B2B - if available - or by standard collection request, any charges incurred as a result of returned SEPA Direct Debit B2B transactions.

# 4. Contact points and further guidance

For questions on the SEPA Direct Debit B2B process that are not covered in this guidance, please contact the EMA's accounting team at accountsreceivable@ema.europa.eu.

Further guidance on how to pay fees and charges levied by EMA can be found on the Agency's website.

# 5. Annex

## *5.1. Checklist for setting up a SEPA Direct Debit B2B mandate*

**Before completing the mandate**

☐ Ensure your organisation has an **active EMA customer account number** (quoted on the EMA invoice)
☐ Confirm that your bank account is a **business (non-consumer) account** eligible for SEPA B2B.

**Completing the mandate**

☐ Use the official **EMA SEPA Direct Debit B2B mandate template**.

☐ Do **not complete the Mandate Reference** (reserved for EMA).

☐ Quote the **EMA customer account number** (quoted on the EMA invoices).

☐ Fill in all **debtor (payer) details** accurately (legal entity name, registered address).

☐ Ensure the bank **account holder name matches exactly** with bank records.

☐ Provide **IBAN/BIC** corresponding to the business account.

☐ Ensure **one mandate per legal entity**, even if bank accounts are shared within a group.

**Signing the mandate**

☐ Have the mandate signed by an **authorised signatory** with legal authority.

☐ If using electronic signature, ensure it is **accepted by your bank and verifiable**.

**Submitting the mandate to EMA**

☐ Send the signed mandate to EMA:

   ☐ By **email (scanned PDF)** to accountsreceivable@ema.europa.eu, or

   ☐ By **post** if signed by hand.

☐ Clearly indicate (template email message/cover letter provided in Section 5.2):

   ☐ Your **EMA customer account number**

   ☐ The **services** for which SEPA DD B2B will be used (Scientific Advice / Certificates / Parallel Distribution).

**Registering the mandate with your bank**

☐ Receive the unique mandate reference number from EMA.

☐ Register the mandate with your **bank before first use** (mandatory step).

☐ Ensure the bank **validates the mandate details**.

**Finalisation**

☐ Confirm internally that **finance and regulatory teams are aligned**.

☐ Ensure **sufficient funds** are available for collections.

☐ **Inform EMA once bank registration is completed** to agree on the first collection date (template email message/cover letter provided in Section 5.2).

### *5.2. TEMPLATES for communication with EMA*

**Submission of SEPA Direct Debit B2B Mandate**

**Subject:** [Customer Account Number] - [Company Name] - Submission of SEPA Direct Debit B2B Mandate

Dear EMA Accounts Receivable Team,

Please find attached the duly completed and signed **SEPA Direct Debit B2B mandate** for the following entity:

- **EMA customer account number:** [Account Number]
- **Legal entity name:** [Company Name]
- **Registered address:** [Address]

We confirm that:

- The mandate has been **signed by an authorised representative** of the company.
- The **bank account provided is a business account** eligible for SEPA B2B transactions.
- The mandate will be **registered with our bank** in accordance with their procedures, upon receipt of the unique mandate reference number from EMA.

We acknowledge the key scheme conditions and accept the following:

- The **invoice constitutes the pre-notification** for SDD B2B collections (the standard 14-day pre-notification period is waived)
- EMA may initiate collection **on the business day following the invoice date**
- Payments are subject to a **three TARGET business day return period**, after which they become final and irrevocable
- Any returned or failed transactions may delay or prevent service provision
- EMA may recover any applicable bank charges related to returned transactions

We would like to use the SEPA Direct Debit B2B method for the following services (please select):

☐ Scientific Advice

☐ Certificates

☐ Parallel Distribution

We kindly request your confirmation of activation of the mandate and communication of the unique mandate reference.

Please let us know if any additional information or documentation is required.

Kind regards, […]

**<u>Confirmation of SEPA Direct Debit B2B Mandate Registration</u>**

**Subject:** [Customer Account Number] - [Company Name] - Confirmation of SEPA Direct Debit B2B Mandate Registration

Dear EMA Accounts Receivable Team,

We hereby confirm that the **SEPA Direct Debit B2B mandate** for:

- **Legal entity name:** [Company Name]
- **EMA customer account number:** [Account Number]
- **Mandate reference number:** [Mandate Number]

has been **successfully registered with our bank**.

In line with the SEPA Direct Debit B2B process, we kindly request your confirmation of the date of the first collection.

We remain at your disposal should any further information be required.

Kind regards, […]