

Standard operating procedure

Title: Amendment, cancellation, waiver or partial waiver of amounts receivable - revenue operations			
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1. Purpose

The purpose of this SOP is to establish a single cross-agency procedure for the correct application of Article 62 of the Financial Regulation applicable to the budget of the European Medicines Agency (FR), and in particular:

- paragraph (4) waiver and partial waiver recovery of established amounts receivable,
- paragraph (5) cancellation of recovery of sums due to the agency including refund of sums received by the agency as a result of a mistake as to a point of law or fact

2. Scope

This SOP is applicable to all divisions and departments of EMA processing financial transactions which involve waiver, cancellation or adjustment of recovery of established amounts receivable in accordance with Articles 62 - 66 of the Financial Regulation.

This SOP <u>does not cover</u> corrections of fee transactions or the issuing of penalty amounts in accordance with Article 8(5) of the pharmacovigilance fee regulation (Regulation (EU) No 658/2014).

3. Responsibilities

It is the responsibility of each financial initiating agent and (delegated) authorising officer to comply with this procedure and the principles of the Financial Regulation, including sound financial management.

Establishment of amounts receivable is the responsibility of the (delegated) authorising officer responsible for the relevant area of operation.



The act of recovery is the responsibility of the accounting officer.

Waiver and partial waiver of the recovery of an established amount receivable is the responsibility of the Executive Director alone and cannot be delegated (Article 3(7) Internal Rules for the execution of the European Medicines Agency's budget).

4. Changes since last revision

SOP updated to reflect new organisational structure and new/revised corporate control documents.

5. Documents needed for this SOP

Template 'Decision to waive, cancel of adjust a recovery of debt' (EMA/678182/2012)

6. Related documents

- <u>Financial Regulation applicable to the budget of EMA, Implementing Rules to the FR and Internal Rules</u>
- SOP/EMA/0137 Recovery of amounts wrongly paid, off-setting of amounts wrongly paid expenditure operations

The list may not be exhaustive.

7. Definitions

ACC: accounting officer

AO: authorising officer

Cancellation: FR, Article 62(5) – The authorising officer shall cancel an established amount receivable in full or in part when the discovery of a mistake reveals that the amount had not been correctly established. Such cancellation shall be by decision of the authorising officer and shall be suitably substantiated

Credit memo: SAP terminology for transaction which reduces or cancels a recovery order (acceptance request/sales order)

ED/AO: the Executive Director in his role as the overall authorising officer of the Agency

FIA: financial initiating agent

Proportionality: the effort and cost involved in the recovery of an established amount shall be proportional to the amount involved

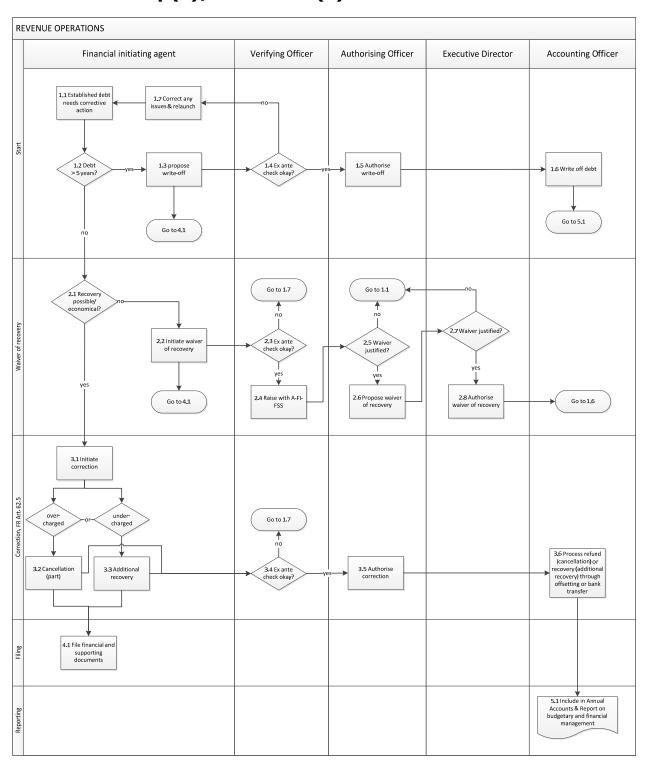
Recovery: FR, Articles 60 and 61 – The process of establishing, authorising and cashing amounts receivable by the agency

Sound financial management: FR, Article 29 - management in accordance with the principles of economy, efficiency and effectiveness

VO: verifying officer

Waiver: FR, Article 62(4) – Where the authorising officer plans to waive or partially waive an established amount receivable, he shall ensure that the waiver is in order and complies with the principle of sound financial management and proportionality. The waiver decision shall be substantiated

8. Process map(s)/flow chart(s)



9. Procedure

Step	Action – Start	Responsibility
1.1.	Information is received that a debt, is being queried, has been wrongly established or cannot be recovered, and that action is needed.	FIA
1.2.	Check if the entitlement is older than 5 years and has not been deferred. If not go to step 2.1.	FIA
1.3.	Propose cancellation/write-off of debt For filing, go to step 4.1.	FIA
1.4.	Carry out ex ante check. If not successful, go to step 1.7. for appropriate action.	VO
1.5.	If transaction is in order, authorise cancellation/writing-off of debt.	AO
1.6.	Write off the outstanding debt For reporting, go to step 5.1.	ACC
1.7.	Correct any issue raised by VO and re-launch transaction. Go to step 1.1.	FIA

Step	Action – waiver of recovery, FR Art. 62(4)	Responsibility
2.1.	Is recovery possible/economical?	FIA
	If yes, go to step 3.1.	
2.2.	Initiate procedure for part or full waiver of recovery of the outstanding	FIA
	debt.	
	Provide clear instructions, documentation of and justification for the	
	proposed waiver. Consult with Legal Department if necessary.	
	For filing, go to step 4.1.	
2.3.	Carry out ex ante check.	VO
	If not successful, go to step 1.7. for appropriate action.	
2.4.	Bring any issues related to cross-agency consistency of fee reductions	VO
	to the attention of A-FI-FSS.	
2.5.	Check if the proposed (part) waiver of recovery is justified.	AO
	If transaction is not in order, go to step 1.1. for appropriate action.	
2.6.	If transaction is in order propose (part) waiver of recovery.	AO
2.7.	Check if the proposed (part) waiver of recovery is justified.	ED
	If not, go to step 1.1. for appropriate action.	
2.8.	If the transaction is in order authorise (part) waiver of recovery.	ED
	For write-off, go to step 1.6	

Step	Action – Corrrection of amounts charged, FR Art. 62(5)	Responsibility
3.1.	Initiate correction by creating a recovery order (SAP transaction F881, acceptance request, type DR or ZG (as in initial recovery)) for the correction amount on the revenue budget item from which the amount was originally charged. Provide clear cross-reference, instructions and justification for the	FIA

Step	Action – Corrrection of amounts charged, FR Art. 62(5)	Responsibility
	recovery order.	
3.2	For amounts overcharged create negative recovery order (SAP	FIA
	transaction F889, Deduction).	
	For filing, go to step 4.1.	
3.3	For amounts undercharged create additional recovery order.	FIA
	For filing, go to step 4.1.	
3.4.	Carry out ex ante check.	VO
	If not successful, go to step 1.7. for appropriate action.	
3.5.	If transaction is in order, authorise recovery order.	AO
3.6	Process refund (cancellation) or recovery (additional recovery)	ACC
	through offsetting or bank transfer	
	For recording, go to step 5.1.	

Step	Action – filing	Responsibility
4.1.	File original financial and supporting (paper) documents,	FIA
	cf. electronic filing, see heading '10. Records'.	

Step	Action - reporting	Responsibility
5.1.	Report in annual accounts and annual report on budgetary and financial	ACC/A-SG-SPB
	management	

10. Records

Electronic filing: DREAM cabinet 08. Financial Management/08.4 Financial Processing/08.40 Individual budget items /relevant budget item/Miscellaneous for completed Word form and scanned version including signature