



Standard operating procedure

Title: Handling of financial procedure for parallel distribution		
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1. Purpose

To enable the processing of financial documents for parallel distribution in a consistent way.

To describe the procedure for processing financial documents for parallel distribution, i.e. preparation and approval of sales orders.

2. Scope

This SOP applies to the Compliance and Inspection Sector only, and should be read in conjunction with the documents listed in section 6.

3. Responsibilities

It is the responsibility of the Head of Sector to ensure that this procedure is adhered to within his/her own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- PD initial notification form received from PD secretariat.
- Cover note (EMEA/57207/2009)
Mgt and Adm\Administration\A – Finance & Budget\VO\A-New structure\VO procedures.



- Checklists tables (EMA/67033/2009)
Mgt and Adm\Administration\A – Finance & Budget\VO\A-New structure\VO procedures.

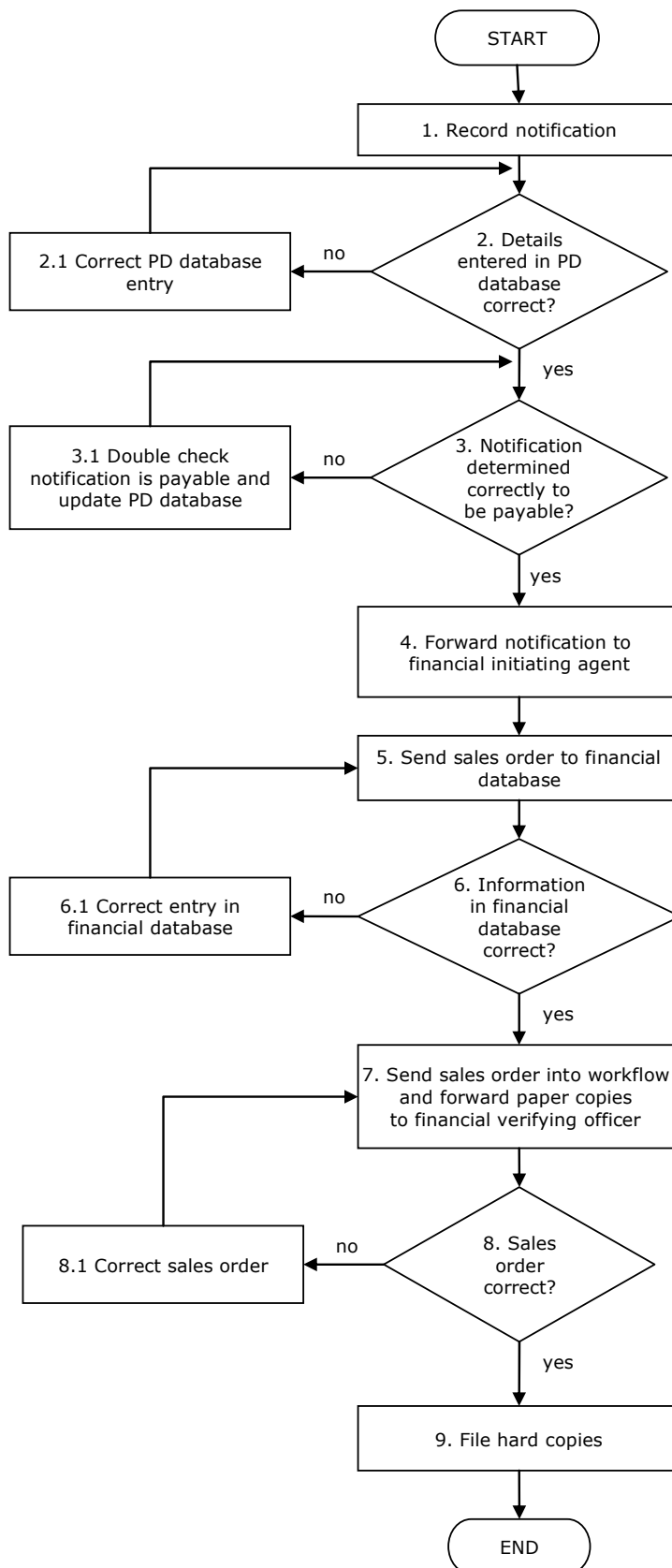
6. Related document

- Council Regulation (EEC) No 297/95 articles 3 and 5, as amended:
ec.europa.eu/health/files/eudralex/vol-1/reg.../reg_1995_297_en.pdf
- Rules for implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures, as amended:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500104381.pdf
- Financial Regulation (FR) of the European Medicines Agency, as amended (Doc.-Ref.: EMA/MB/216485/2009).
- Implementing Rules (IR) - Rules for the implementation of the Financial Regulations applicable to the budget of the European Medicines Agency (Doc.-Ref.: EMA/MB/281870/2010).
- SOP/INSP/2014: Processing of parallel distribution initial notifications.
- WIN/INSP/2036: Determination of the fee for a parallel distribution notification.

7. Definitions

PD database	Parallel distribution database of the EMA
P-CI	Compliance and Inspections Sector in the Patient Health Protection Unit
PD	Parallel Distribution
PD assessor	PD assistant
Operational verifying officer PD	Section Head or other delegated administrator/assistant

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



9. Procedure

Step	Action	Responsibility
Operational initiation of sales order		
1	Record request of PD initial notification received in PD database and determine whether payable or non-payable (according to WIN/INSP/2036).	PD assessor (Operational initiating agent)
Operational verification of sales order		
2	<p>Details entered in PD database correct?</p> <p>Check that the details entered correspond to information submitted by company.</p> <p>If, yes, go to step 3.</p> <p>If no, return documents to PD assessor (operational initiating agent) and ask to amend data entered in PD database. Go to step 2.1.</p>	Operational verifying officer PD
2.1	<p>Amend entry in PD database as appropriate and submit documents to operational verification.</p> <p>Go to step 2.</p>	PD assessor (Operational initiating agent)
3	<p>Check whether notification has been determined correctly to be payable by reviewing all notifications submitted by the company for the concerned product in the PD database.</p> <p>If yes, sign both copies of the notification form and go to step 4.</p> <p>If no, return documents to PD assessor requesting to check. Go to step 3.1.</p>	Operational verifying officer PD
3.1	<p>Double check that it is a payable notification, update PD database and resubmit to operational verifying officer.</p> <p>Go to step 3.</p>	PD assessor (Operational initiating agent)
4	<p>Forward one copy of the payable notification to the financial initiating agent. Distribute the second notification copy to the PD assessor for further processing and finalisation of the procedure (according to SOP/INSP/2014).</p> <p>Distribute the non-payable notifications among the PD assessors for further processing and finalisation of the procedure (according to SOP/INSP/2014).</p>	Operational verifying officer PD
Financial initiation of sales order		
5	Send sales order from the PD database to the financial database.	Financial initiating agent
6	Ensure that the following information in the financial database corresponds with the PD initial notification form:	Financial initiating agent

Step	Action	Responsibility
	<ul style="list-style-type: none"> Sold-to-party is identical to company that submitted notification Administrative fees are applied correctly (according to Financial Regulation and Implementing Rules) <p>If yes, go to step 7.</p> <p>If no, go to step 6.1.</p>	
6.1	<p>Correct entry in financial database according to information on the PD initial notification form.</p> <p>Go to step 6.</p>	Financial initiating agent
7	<p>Send the sales order into the workflow. Export the list of sales orders to Excel and save it in the designated DREAM folder.</p> <p>Forward a signed print out of the Excel file along with the paper copies of the PD initial notifications to the financial verifying officer.</p>	Financial initiating agent
Financial verification of sales order		
8	<p>Is the sales order correct?</p> <p>Verify the following information by checking the sales order against the information contained in the PD initial notification forms:</p> <ul style="list-style-type: none"> Company details. Amount of the administrative fee. <p>If yes, return the documents to financial initiating agent and go to step 9.</p> <p>If no, reject it in the workflow, inform the financial initiating agent about what information is incorrect and send it back for correction.</p> <p>Go to step 8.1.</p>	Financial verifying officer
8.1	<p>Correct the sales order and send it back to the financial verifying officer.</p> <p>Go to step 7.</p>	Financial initiating agent
9	<p>File the hardcopies of the financial report in the designated folder located in the financial initiating agent's office.</p>	Financial initiating agent

10. Records

When the processing of financial documents for parallel distribution is completed and approved, the retention of the hard copy will be the responsibility of the P-CI Sector. Retention time 7 years after end of project according to Business Classification Scheme.