EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Processing of parallel distribution initial notifications		
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Lead author	Approver	Effective date: 19-JUL-12
Name: Diana Lupescu	Name: Francisco Penaranda	Review date: 19-JUL-15
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1. Purpose

The purpose of this SOP is to define the procedure for processing the parallel distribution notifications in a consistent way.

2. Scope

This SOP applies to the Parallel Distribution and Certificates (P-CI-PDC) section, in the Compliance and Inspection sector in the Patient Health Protection unit.

3. Responsibilities

It is the responsibility of the Section Head to ensure that this procedure is adhered to within his/her own section. 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

The following documents are located on the X:Drive (X:\Templates\Others\Parallel Distribution):

- Checklist for fee verification (label).
- Initial notification form (template).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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- Checklist for licence verification (label).
- Email template for reminders for outstanding initial notifications.
- Checklist and handling time initial.

6. Related documents

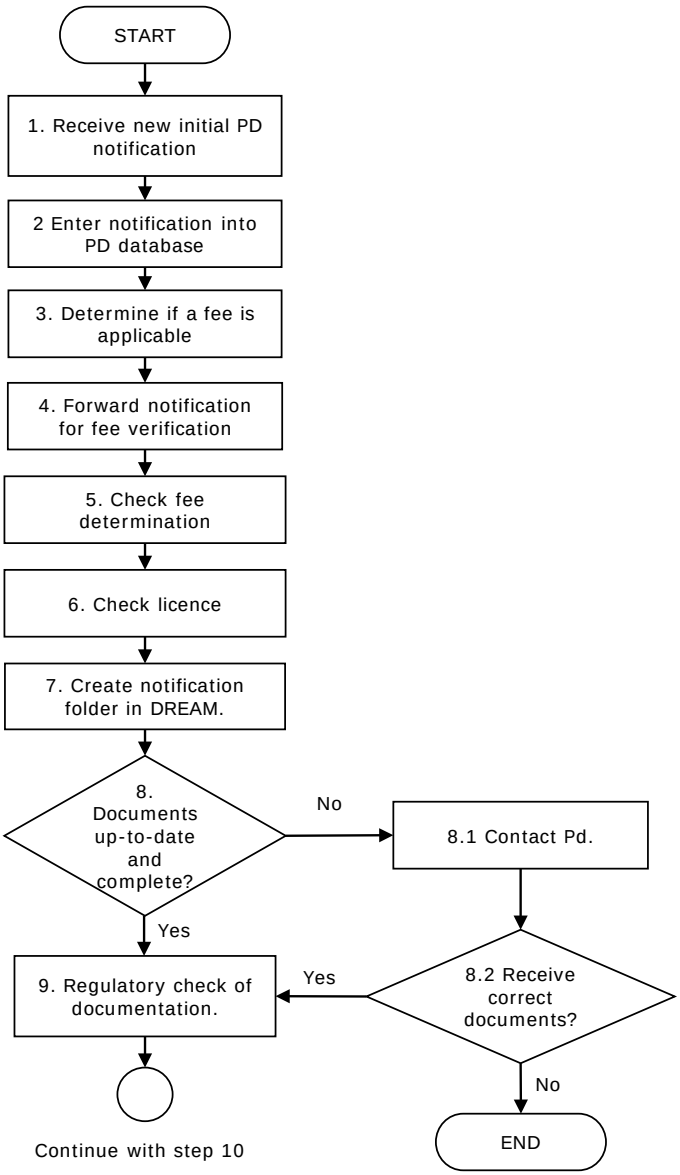
- SOP/INSP/2013 Handling of financial procedure for parallel distribution.
- WIN/INSP/2036 Determination of the fee for a parallel distribution notification.
- WIN/INSP/2038 Checking licences for parallel distribution.
- WIN/INSP/2031 Regulatory check of initial notifications of parallel distribution.
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use, Revision 1, Doc Ref: ENTR/F/2/SF/jr (2009)D/869, available on the European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for human use > EudraLex > Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use.
- Guideline on the packaging information of medicinal products for human use authorised by the Community, Final – Revision 13, Doc Ref: F2/SM D(2008), available on the European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for human use > EudraLex > Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use.
- Guideline for the specifications of e-submissions of parallel distribution notification documents, Version 2.1, EMA/INS/25561/2010, available on the EMA website: Home > Regulatory > Human medicines > Parallel distribution > Guidance.
- EMA post-authorisation Guideline on parallel distribution is available on the EMA website: Home > Regulatory > Human medicines > Parallel distribution > Guidance

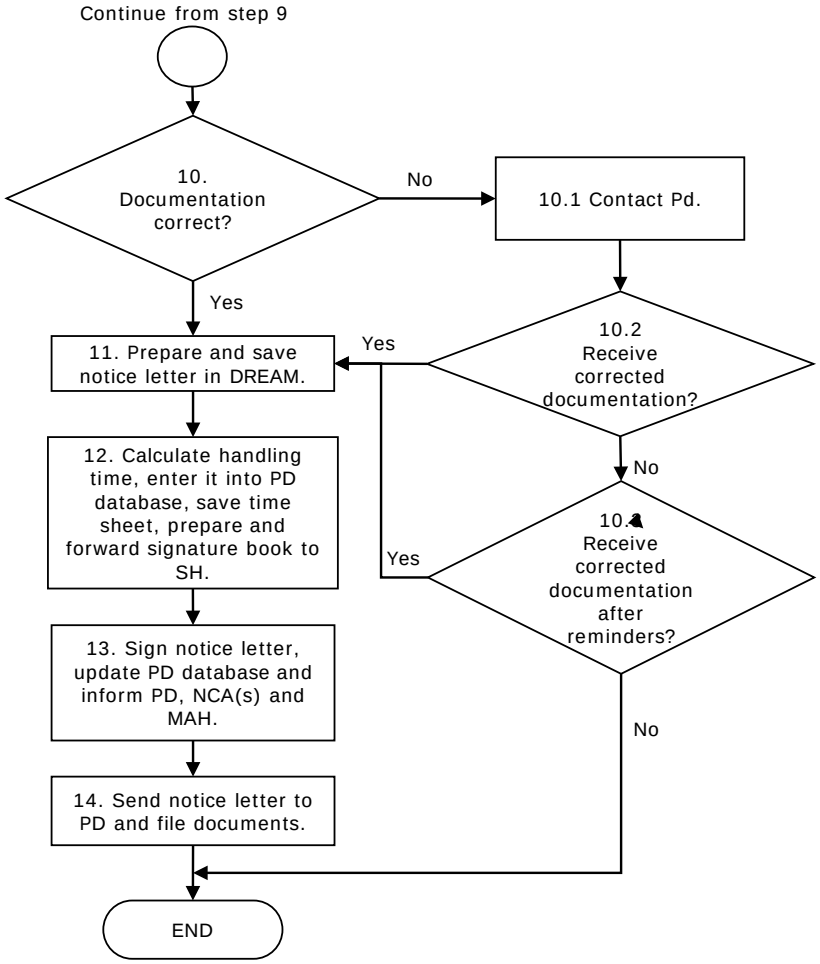
7. Definitions

DREAM	Document Records Electronic Archive Management: EMA web-based system for electronic archive of documents.
E-Submission	Electronic submission of parallel distribution notification form.
Eudralink	the European medicines regulatory network's secure file transfer system used for exchanging information for regulatory purposes.
IL	Inner labelling of the medicinal product (blister label, vial label etc.).
MAH	Marketing authorisation holder.
MIA	Manufacturing and Importation Authorisation.
MSD	Member state of destination of the medicinal product.
NCA	National competent authority.
OL	Outer labelling of the medicinal product (e.g. carton label).
P-CI-PDC	Parallel Distribution and Certificates section, Compliance and Inspection sector, Patient Health Protection unit.

PD	Parallel distribution.
Pd	Parallel distributor.
PD assessor	Assistant in the Parallel Distribution and Certificates section, responsible for processing the parallel distribution notifications for centrally-authorised products.
PD database	EMA's parallel distribution database.
PL	Package leaflet of the medicinal product.
SH	P-CI-PDC Section Head.
TVT	Text Verification Tool. The text verification tool is a Windows-based software capable of comparing any original text document with the formatted version of the text prepared for printing.
WDA	Wholesaler's Distribution Authorisation.

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




Continue from step 9
10. Documentation correct?
No
10.1 Contact Pd.
Yes
11. Prepare and save notice letter in DREAM.
Yes
10.2 Receive corrected documentation?
No
12. Calculate handling time, enter it into PD database, save time sheet, prepare and forward signature book to SH.
Yes
10.3 Receive corrected documentation after reminders?
No
13. Sign notice letter, update PD database and inform PD, NCA(s) and MAH.
14. Send notice letter to PD and file documents.
END

9. Procedure

Step	Action	Responsibility
1.	Receive new initial PD notification, electronically via Eudralink, into the PD e-submission inbox in Outlook: Public Folders/All Public Folders/Workflow/PD Esubmission). Note: This responsibility is assigned to the PD assessor in charge of the mail week (rota system to manage the incoming mail).	PD assessor (Operational initiating agent)
2.	Enter the notification into the PD database.	PD assessor (Operational initiating agent)
3.	Determine if a fee is applicable for the notification, according to WIN/INSP/2036.	PD assessor (Operational initiating agent)
4.	Forward the notification to the person responsible for fee verification.	PD assessor (Operational initiating agent)
5.	Check if the fee has been correctly determined in step 3 and update PD database, according to SOP/INSP/2013.	PD operational verifying officer
6.	Check if an (updated) licence (WDA and/or MIA) is required, according to WIN/INSP/2038.	PD assessor (Operational initiating agent)
7.	Create a new folder for the notification in DREAM. Re-open the PD e-submission inbox and save the Eudralink attachments in the newly-created DREAM folder. Confirm receipt of the Eudralink email.	PD assessor (Operational initiating agent)
8.	Check the following points: • information on the form is complete and correct according to the checklist published on EMA public website: Home > Regulatory > Human medicines > Parallel distribution > Guidance > Parallel Distribution: Checklist Initial Notification. • colour copies of the OL and IL, PL, specific mechanism letter (if applicable). • details of the repackager and required repackaging conditions for the product. • PL up-to-date. • cover letter/form is signed by the Pd. Fill in the 'Validation' tab in PD database. If all the documentation is complete and up-to-date, send the validation email/ letter to the Pd, save it into the DREAM folder and go to step 9. If the documentation is not complete and/or up-to-date, go to step	PD assessor (Operational initiating agent)

Step	Action	Responsibility
	8.1.	
8.1	Send an 'Incorrect information letter/ email' to the Pd. Save it in the DREAM folder.	PD assessor (Operational initiating agent)
8.2	If the company submits the required / corrected documentation, go to step 9. If the company fails to submit correct documentation within 15 days, the procedure ends.	PD assessor (Operational initiating agent)
9.	Start the regulatory check of the documentation, as described in WIN/INSP/2031.	PD assessor (Operational initiating agent)
10.	Is submitted documentation in accordance with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation? If yes, go to step 11. If no, go to step 10.1.	PD assessor (Operational initiating agent)
10.1	Email the comments and/or the PDF copy with annotations to the Pd, indicating 15 working days as a deadline for implementing them.	PD assessor (Operational initiating agent)
10.2	If the correct documentation is received, continue with step 11. If no reply, continue with step 10.3.	PD assessor (Operational initiating agent)
10.3	Send up to 3 reminders (with a 15 calendar day deadline for each of them) to the Pd before closing down the application. In the final reminder, announce that the notification will be rejected and copy the PDC Section Head and Financial Initiating Agent. Close down the procedure if no reply is received. If correct documentation is received, continue with step 11.	PD assessor (Operational initiating agent)
11.	Prepare the notice letter for finalisation of the procedure and save it in DREAM.	PD assessor (Operational initiating agent)
12.	Calculate the handling time for the regulatory check using the checklist, enter it into the PD database and save the updated handling time sheet in the initial notification folder. Prepare the documentation for final signature with the notice letter, the notification file and handling time sheet, if applicable prepare post-notice comments (e.g. recommendation on inclusion of the name of the repackager and/or Pd in the PL). Forward the signature book to the P-CI-PDC Section Head or back-up.	PD assessor (Operational initiating agent)
13.	Sign the notice letter and update the PD database. An email is sent	PD Section Head

Step	Action	Responsibility
	to the Pd, NCA(s) and MAH with information on the finalisation of the notification procedure. Include any comments in the signature book. Return the documentation to the PD assessor (Operational initiating agent).	
14.	Send out the post-notice comments (if any) to the Pd and save the correspondence in DREAM. Insert the comments in the PD database ('Notice' tab). Duplicate the signed notice letter and send the original notice letter to the Pd via post. Add a copy of the notice letter to the notification file. Upon receipt of the reply to the post-notice comments from the Pd, add the reply to the notification file. File the notification file alphabetically and per company in the appropriate binders in the PD filing area.	PD assessor (Operational initiating agent)

10. Records

The following documents are saved electronically in the product folder of the parallel distributor in DREAM:

- Incorrect info letter(s) or e-mail(s), if applicable (correspondence indicating the issues to be corrected by the PD before validation stage).
- Validation letter.
- Regulatory check request and outcome.
- Comments letter(s) or e-mail(s), if applicable.
- Notice letter.
- Handling time sheet.
- Any other (e-mail) correspondence with the parallel distributor on the notification.
- Notification form, colour copies, package leaflet in case of electronic submission.
- Files extracted from the TVT project (PDF report, PDF copy with annotations).

The following documents are filed in paper in the binders of the parallel distributor in the PD area:

- Notification form indicating fee verification.
- Signed notice letter.

Electronic copies of any correspondence, as well as the Text Verification Tool (TVT) report and the TVT copy with annotations are filed in the product folder in DREAM (Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Companies). The retention time is minimum 10 years.