EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Processing of annual update notifications for parallel distribution		
Status: **PUBLIC**		Document no.: SOP/INS/2058
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Signature: on File	Signature: on File	Supersedes: n/a
Date: 06-MAY-15	Date: 06-MAY-2015	TrackWise record no.: 4164

1. Purpose

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

2. Scope

This SOP applies to the Parallel Distribution and Certificates (P-CI-PDC) Service, in the Compliance and Inspection Department in the Inspections and Human Medicines Pharmacovigilance Division.

3. Responsibilities

It is the responsibility of the Head of Service to ensure that this procedure is adhered to within his own service. 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):

- Template for annual update notification form.
- Template e-mails for reminders for outstanding annual update notifications.

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- Templates for annual update notice letters.

6. Related documents

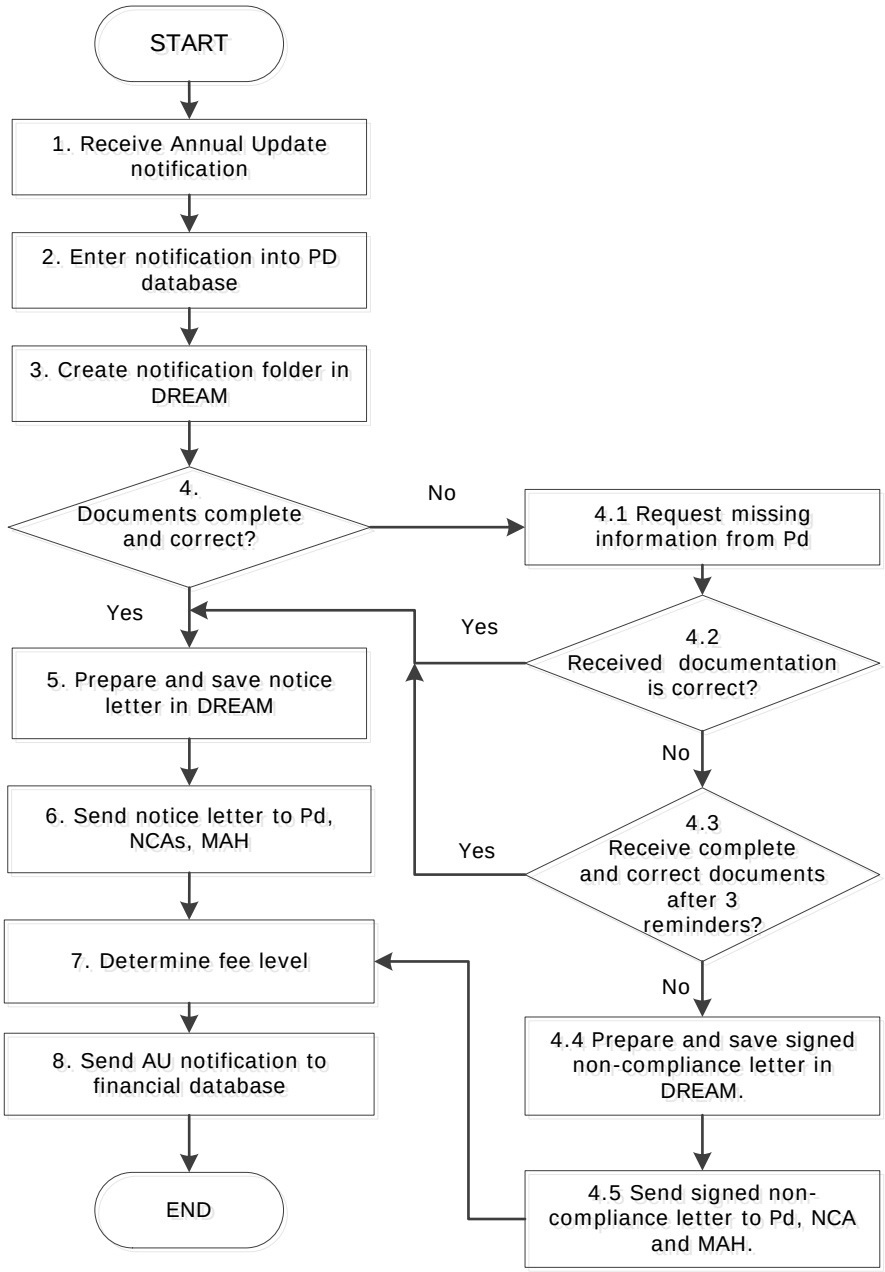
- SOP/INSP/2039 Processing of parallel distribution notifications of a change.
- WIN/INSP/2031 Regulatory check of initial notifications of parallel distribution.
- WIN/INSP/2038 Checking licences for parallel distribution.
- Guideline on the readability of the labelling and package leaflet of medicinal 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 > Legal framework > 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 Union, Final – Revision 14 (July 2013), available on the European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for human use > Legal framework > EudraLex > Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use.
- Guideline on the packaging information of veterinary medicinal products authorised by the Community, Revision 2c, Doc Ref: DGENTR/F/2/KK D(2008), available on the European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for veterinary use > Legal framework > EudraLex > Volume 6 - Notice to applicants and regulatory guidelines for medicinal products for veterinary use.
- EMA frequently asked questions about parallel distribution is available on the EMA website: Home > Human regulatory > Parallel distribution
- Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures, as amended: EMA public website > Home > Human regulatory > Fees

7. Definitions

AU	Annual update.
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.
HoS PDC	P-CI-PDC Head of Service.
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.
“New” Member State(s)	Terminology internally used to describe the Member States that joined the European Union after 2004 (e.g. Czech Republic, Cyprus, Estonia, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia, Slovakia, Bulgaria, Romania, Croatia)
OL	Outer Labelling of the medicinal product (e.g. carton label).
“Old” Member State(s)	Terminology internally used to describe the Member States that joined the European Union before 2004 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom).
P-CI-PDC	Parallel Distribution and Certificates Service, Compliance and Inspection Department, Inspections and Human Medicines Pharmacovigilance Division.
PD	Parallel distribution.
Pd	Parallel distributor.
PD assessor	Assistant in P-CI-PDC, responsible for processing the parallel distribution notifications for centrally-authorised products.
PD database	EMA’s parallel distribution database for internal access only.
PL	Package Leaflet of the medicinal product.
Specific mechanism	Mechanism introduced by the Accession Treaties signed between the EU and each “new” Member State, which puts in place a transitional period to the full application of the principle of the free movement of goods to prevent parallel trade in pharmaceutical products that lack equivalent intellectual property right protection.
Specific mechanism letter	The letter sent by the Pd to the patent holder/beneficiary, notifying them about their intention to parallel-distribute a medicinal product from one or several “new” Member State(s) to one or several “old” Member State(s).Text comparison report Report generated by a software which is 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)



9. Procedure

Step	Action	Responsibility
1.	Receive annual update notification electronically via Eudralink, into the PD e-submission changes inbox in Outlook: Public Folders/All Public Folders/Chrono In/Workflow/PD Esubmission Changes.	PD assessor
2.	Enter the notification into the PD database.	PD assessor
3.	Create notification folder in DREAM and save the Eudralink attachments in the newly-created folder. Confirm receipt of the Eudralink email. Note: Folder's name convention: Medicinal Product_pharmaceutical form_record number generated by the PD database; e.g. (Product X_Tablet_01234)	PD assessor
4.	Perform regulatory check of the following documentation, as described in SOP/INSP/2039, WIN/INSP/2031 and/or WIN/INSP/2038 as applicable: • Application form. • Cover letter. • Pd's licence, if applicable. • Repackager's licence, if applicable. • Colour copies of the OL and IL of each route of administration of a particular pharmaceutical form. • Up-to-date PL in editable PDF or Word of each route of administration of a particular pharmaceutical form. • Specific mechanism letter (if applicable). • Report extracted from text comparison software, if applicable. If all the documentation is complete and in accordance with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation, go to step 5. If the documentation is not complete and/or in accordance with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation, go to step 4.1.	PD assessor
4.1	Send an email to the Pd requesting missing or correct documentation indicating 10 working days as deadline. Save it in the DREAM folder.	PD assessor
4.2	If the company submits the required documentation, go to step 5. If no reply, go to step 4.3.	PD assessor
4.3	Send up to 3 reminders to the Pd before closing the procedure. Note: Send first reminder on week 3 by e-mail. Send second reminder on week 5 by e-mail, third reminder on week 7 by post	

Step	Action	Responsibility
	onofficial headed letter signed by HoS and indicating 10 working days as deadline. If no reply is received within the set deadline, go to step 4.4 If required documentation is received within the deadline, continue with step 5 .	
4.4	Prepare non-compliance letter, get it signed by HoS and save the signed non compliance letter in DREAM.	PD assessor
4.5	Send signed non-compliance letter via post to Pd only and via e-mail to Pd, NCA and MAH and continue with step 7.	PD assessor
5.	Generate notice letter from PD database and save it in DREAM.	PD assessor
6.	Send notice letter via e-mail to Pd, NCA and MAH.	PD assessor
7.	Determine fee level based on the documentation submitted and made available by the Pds, as described below: • Assign REDUCED fee ONLY if regulatory check of the package leaflet is required AND the text comparison report has been submitted and meets the conditions laid down by the Agency for the acceptance of the report. • Assign FULL fee if the text comparison report is required (changes to package leaflet) but has NOT been submitted, is NOT required (no update of the package leaflet) or has been submitted but did NOT meet the conditions laid down by the Agency for the acceptance of the report. • Assign NO FEE if there are no changes or all presentations on the application form are marked dormant.	PD assessor
8.	Transfer annual update notification from the PD database to the financial database.	PD assessor

10. Records

The following documents are saved electronically in the annual update folder of the parallel distributor in DREAM (Cabinets/ 01. Evaluation of Medicine/ Parallel Distribution/ Human Medicines/ Companies for human medicinal products and Cabinets/ 01. Evaluation of Medicine/Parallel Distribution/Veterinary Medicines/Companies for veterinary medicinal products):

- Cover letter
- Notification form, colour copies, package leaflet.
- Text comparison report submitted by the Pd, if applicable.
- All correspondence with the parallel distributor on the notification.
- Regulatory check outcome.
- Notice or non-compliance letter.

- Files extracted from the text comparison software (PDF report, PDF copy with annotations), if applicable.

The retention time is 15 years from closure of procedure.