EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: Processing of parallel distribution notifications of a change | | |
|---|---|---|
| Status: **PUBLIC** | | Document no.: SOP/INSP/2039 |
| Lead author | Approver | Effective date: 27-SEP-12 |
| Name: Diana Lupescu | Name: Francisco Penaranda | Review date: 27-SEP-15 |
| Signature: On file | Signature: On file | Supersedes:<br>n/a |
| Date: 25-SEP-12 | Date: 25-SEP-12 | TrackWise record no.: 3353 |

## 1. Purpose

The purpose of this SOP is to define the procedure for processing parallel distribution notifications of a change 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):

- Notification of a change form (template).
- Checklist and handling time changes.

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
An agency of the European Union

## 6. Related documents

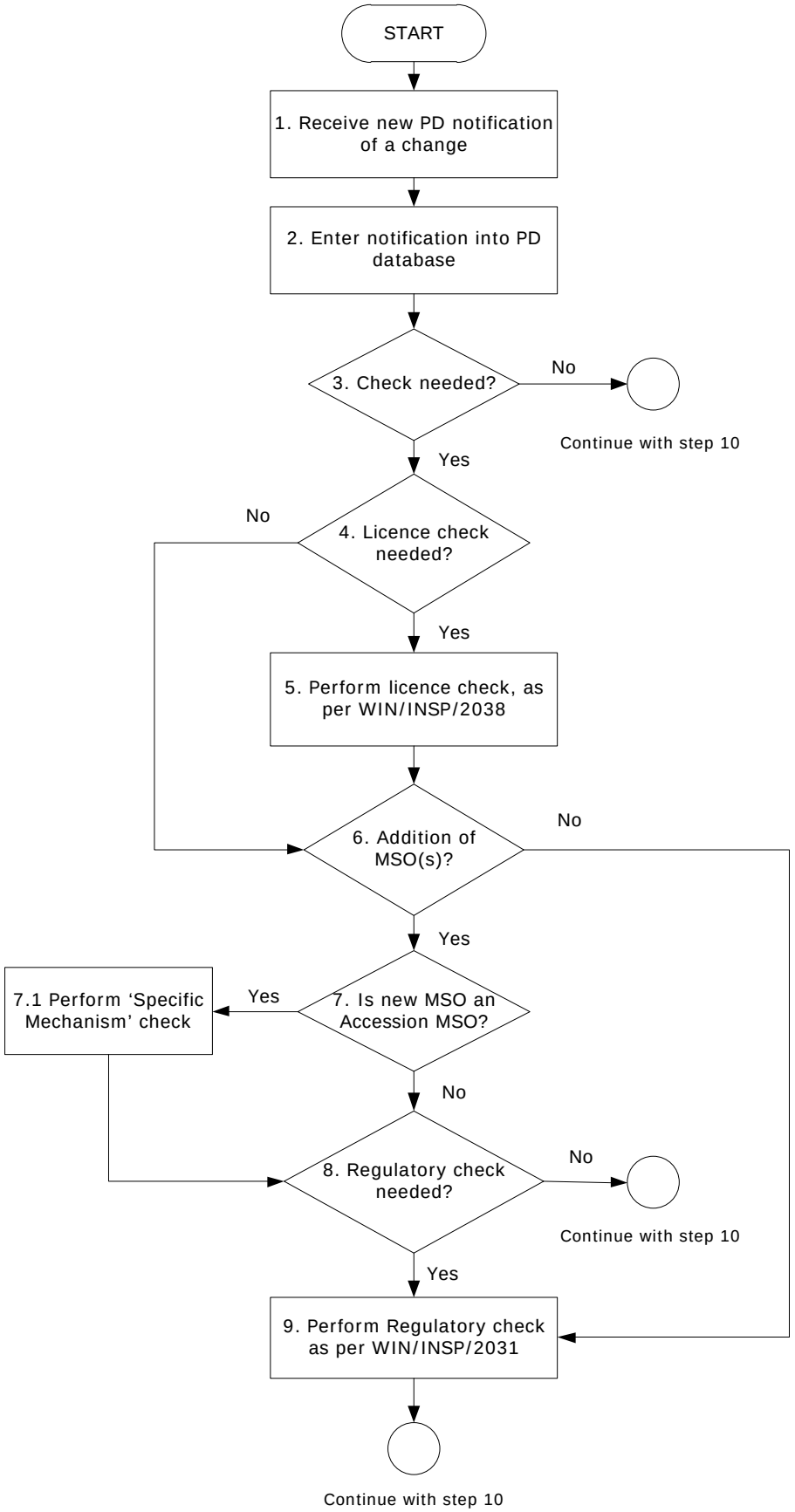
- WIN/INSP/2031 Regulatory check of initial notifications of parallel distribution.
- WIN/INSP/2038 Checking licences for parallel distribution.
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use, Revision 1, Doc Ref: ENTR/F/2/SF/jr (2009)D/869, available on the European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for human use > 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.
- EMA Post-authorisation guidance on parallel distribution, EMEA/Ho/2368/Rev 4, available on the EMA website: Home > Regulatory > Human medicines> Parallel distribution > Guidance.

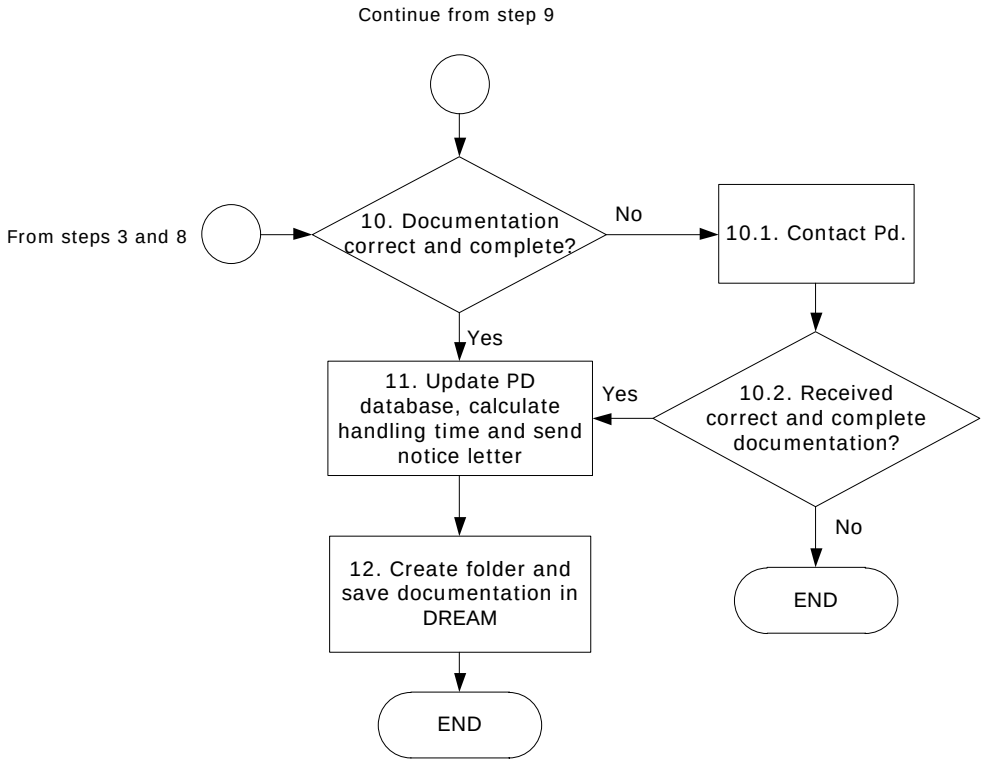
## 7. Definitions

| | |
|---|---|
| 1-month-prior letter | Letter that the Pd sends to the patent holder/ beneficiary, notifying them about their intention to parallel-distribute a medicinal product from one or several Accession Member State(s) to one or several 'old' Member State(s); |
| Accession Member States | Member States that joined the European Union in 2004 and afterwards (e.g. Czech Republic, Poland, Bulgaria etc.); |
| DREAM | Document Records Electronic Archive Management: EMA web-based system for electronic archive of documents; |
| 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 (e.g. blister label, vial label etc.); |
| MAH | Marketing authorisation holder; |
| MIA | Manufacturing and Importation Authorisation; |
| MSD | Member state of destination of the medicinal product; |
| MSO | Member state of origin of the medicinal product; |
| NCA | National competent authority; |
| OL | Outer labelling of the medicinal product (e.g. carton label); |
| 'Old' Member States | Member States that joined the European Union before 2004 (e.g. Germany, United Kingdom etc.); |
| 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; |
| Specific Mechanism | mechanism introduced by the Accession Treaties signed between the EU and each Accession 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; |
| 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
From steps 3 and 8
10. Documentation correct and complete?
No
10.1. Contact Pd.
Yes
11. Update PD database, calculate handling time and send notice letter
Yes
10.2. Received correct and complete documentation?
No
12. Create folder and save documentation in DREAM
END
END

# 9. Procedure

| Step | Action | Responsibility |
|---|---|---|
| 1. | Receive new PD notification of a change, electronically via Eudralink, into the PD e-submission changes inbox in Outlook: Public Folders/All Public Folders/Workflow/PD Esubmission Changes.<br><br>Note: This responsibility is assigned to the PD assessor in charge of the changes week (rota system to manage the incoming notifications of a change). | PD assessor (Operational initiating agent) |
| 2. | Enter the notification into the PD database. | PD assessor (Operational initiating agent) |
| 3. | Is a check of the documentation needed?<br>• For the following scopes of change: *removal of MSD(s) and/or MSO(s) and/or addition of a trademark statement onto the product information (IL, OL, PL)*, no check of the documentation is needed.<br>• For all other scopes of changes, a detailed check is needed.<br>If yes, go to step 4.<br>If no, go to step 10.<br>Note: if the scope of change includes '*removal of a repackager'* first determine if there are products for which this repackager is declared as the only repackager used. If there are, contact Pd and request replacement repackager. If no, continue with step 10.<br>If the scope of change includes *'addition of the Pd and repackager details in the PL'* first determine if the details are in line with the WDA/MIA. If yes, continue with step 10. If no, contact Pd. | PD assessor (Operational initiating agent) |
| 4. | Determine if a licence check needs to be performed according to the scope(s) of change declared on the form.<br>• If the scope of change is *addition of a repackager; change in the address of the Pd and/or the repackager,* a licence check is required. Go to step 5.<br>• For all other scopes of changes, a licence check is not required. Go to step 6. | PD assessor (Operational initiating agent) |
| 5. | Perform a licence check, as described in WIN/INSP/2038. | |
| 6. | Is the scope of change *addition of MSO(s)?*<br>• If yes, go to step 7.<br>• For all other scopes of changes, go to step 9. | PD assessor (Operational initiating agent) |
| 7. | Determine if some or all of the new MSO(s) are Accession MSOs.<br>• If yes, go to step 7.1.<br>• If no, go to step 8. | PD assessor (Operational initiating agent) |
| 7.1 | Perform a 'Specific Mechanism' check by determining the following:<br>• whether a copy of the 1-month-prior letter has been provided by the Pd;<br>• whether the 1-month-prior letter is signed and dated at least 1 month before the submission date; | PD assessor (Operational initiating agent) |

| Step | Action | Responsibility |
|---|---|---|
| | • whether the 1-month-prior letter clearly mentions:<br>– all the Accession MSOs declared on the form;<br>– the MSD(s);<br>– the name and address of the Pd and of the MAH;<br>– the name of the medicinal product or at least the active substance. | |
| 8. | Determine if a regulatory check needs to be performed according to the scope(s) of change declared on the form.<br><br>A regulatory check is required for the following scopes of changes:<br><br>• *update of the OL, IL and/or PL;*<br>• *addition of reboxing as a repackaging method;*<br>• *addition of re-labelling as repackaging method;*<br>• *addition of MSD(s);*<br><br>Note: When adding a new MSD, check if there are any Accession MS among the previously added MSO(s). If yes, perform a specific mechanism check as described in step 7.1 in addition to the regulatory check.<br><br>• *transfer of the notice for PD from one Pd to another Pd.*<br>• *addition of MSO(s)* only when the previously added MSO and MSD share the same language.<br><br>If a regulatory checked is needed, continue with step 9.<br>If it is not needed, continue with step 10. | PD assessor (Operational initiating agent) |
| 9. | Perform a regulatory check of the OL, IL and/or PL, according to 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 latest marketing authorisation?<br>Is submitted documentation complete (e.g. 1-month-prior letter enclosed; colour copies of the OL or IL submitted etc.)?<br>If yes, go to step 11.<br>If no, go to step 10.1. | PD assessor (Operational initiating agent) |
| 10.1 | Email the comments to the Pd, indicating 15 working days as a deadline for implementing them and submitting the corrected documentation. | PD assessor (Operational initiating agent) |
| 10.2 | If the correct and complete documentation is received, continue with step 11.<br>If no reply or no correct documentation is received, close down the procedure. | PD assessor (Operational initiating agent) |
| 11. | Calculate the handling time using the checklist and update the PD database. An email is sent to the Pd, NCA(s) and MAH with a copy | PD assessor (Operational |

| Step | Action | Responsibility |
|---|---|---|
| | of the Notice letter. | initiating agent) |
| 12. | Create a new folder for the notification in DREAM. Re-open the PD e-submission changes inbox, confirm receipt of the Eudralink email and save the Eudralink attachments, any related correspondence and the email containing the Notice in the newly-created DREAM folder. | PD assessor (Operational initiating agent) |

# 10. Records

When the procedure is completed, the following documents are saved electronically in the product folder of the Pd in DREAM (Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Companies):

- Notification of a change form, cover letter, colour copies, package leaflet, 1-month-prior letter;
- All correspondence indicating the issues to be corrected by the Pd before the finalisation of the procedure;
- Files extracted from the TVT project (PDF report, PDF copy with annotations);
- Email with the Notice letter that is sent to the Pd, MAH and NCA(s);
- Any other correspondence with the Pd on the notification of a change.

The retention time is minimum 10 years.