EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Regulatory check of initial notifications of parallel distribution		
Applies to: Compliance and Inspections Sector, Parallel Distribution and Certificates Section		
Status: **PUBLIC**		Document no.: WIN/INSP/2031
Lead Author	Approver	Effective Date: 19-JUL-12
Name: Diana Lupescu	Name: Francisco Penaranda	Review Date: 19-JUL-15
Signature: On file	Signature: On file	Supersedes: n/a
Date: 16-JUL-12	Date: 16-JUL-12	TrackWise record no.: 2981

1. Changes since last revision

New WIN.

2. Records

- 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.
- 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.
- Community Register of Medicinal Products for human use: European Commission website: Homepage > Departments (Directorates-General) and services > Health and Consumers (SANCO) > Health > Medicinal products for human use > Community Register > Access to the Community Register.

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

- EPAR: EMA homepage > Find medicine > Human Medicines.
- EMA post-authorisation Guideline on parallel distribution is available on the EMA website: Home > Regulatory > Human medicines > Parallel distribution > Guidance.
- Email template for reminders for outstanding initial notifications, located on the X:Drive (X:\Templates\Others\Parallel Distribution).

3. Instructions

List of abbreviations

DREAM	Document Records Electronic Archive Management: EMA web-based system for electronic archive of documents.
EPAR	European public assessment report.
IL	Inner labelling of the medicinal product (e.g. blister label, vial label, etc.).
MA	Marketing authorisation.
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 in the Patient Health Protection unit.
PD	Parallel distribution.
Pd	Parallel distributor.
PD assessor	Assistant in the PDC 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.
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.

When submitting a new initial notification, the parallel distributor (Pd) provides the Agency with colour copies of the re-labelled/ re-boxed medicinal product, as well as a copy of the package leaflet (PL) in the language of the member state of destination (MSD). During the regulatory check of initial notifications, the parallel distribution (PD) assessor (Operational initiating agent) performs a detailed verification of the submitted outer labelling (OL), inner labelling (IL) and PL against the latest version of the marketing authorisation, published on EMA and/or European Commission website. The PD assessor (Operational initiating agent) also checks whether the product information submitted by the Pd is in accordance with the guideline on readability of the labelling and package leaflet of medicinal products for human use and guideline on packaging information of medicinal products.

This WIN should be read as a detailed description of step 12 of SOP/INSP/2014: Processing of parallel distribution initial notifications.

Step	Action	Responsibility
1.	Find the latest version of the MA, by checking both the Community Register of Medicinal Products for human use published on the European Commission website and the EPAR on the EMA website. Save the up-to-date MA on the L: drive.	PD assessor (Operational initiating Agent)
2.	Perform the following checks: • Revision date of the PL: verify whether it is the latest date. • OL and IL: detailed comparison with the latest MA. • Presence of the name and address of the Pd, repackager, marketing authorisation holder and original manufacturer on OL. • Manufacturer on the OL should be the same as in the PL. • Presence of the information in Braille on OL (if applicable). • Original blue box covered and replaced by the blue box for the MSD. • Batch number and expiry date on OL and IL in the language of the MSD. • No preffix or suffix is added to the orginal batch number. • Adequate font size of the text on the labelling and PL in accordance with the guidelines on readability. • Particular topics for certain languages (e.g. 'in German, the preferred term for MAH is 'Zulassungsinhaber') or for certain products ('Once daily'), as detailed in the PD reminder document. • The same EU number is mentioned on OL and notification form. • All sections of IL are labelled (if applicable). • In case of change of packsize, check if the new packsize is authorised. A list of all authorised presentations are published for each product in the EPAR. • Any other product specific issues relevant for the presentation.	PD assessor (Operational initiating agent)
3.	Compare the PL with the latest MA using TVT. Extract a PDF report and a PDF copy with annotations (if any) from the TVT project. Save them in DREAM. Fill in the 'Regulatory check' tab in the PD database. Escalate any regulatory/legal issues to P-CI-PDC Section Head, if necessary. Consult the regulatory and/or legal colleagues for specific advice when required.	PD assessor (Operational initiating agent)
4.	Proceed with step 13 of SOP/INSP/2014: Processing of parallel distribution initial notifications.	PD assessor (Operational initiating agent)