EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Checking licences for parallel distribution		
Applies to: Parallel Distribution Secretariat within the Compliance and Inspection Sector - Parallel Distribution and Certificates Section		
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1. Changes since last revision

Updated to reflect the new organisational names in the Agency and the new corporate identity.

Updated to reflect the changes in procedure introduced by the use of EudraGMP.

2. Records

- Paper copies of the Wholesaler's Distribution Authorisation and/or Manufacturing Importing Authorisation are filed alphabetically and per company in the licence folders in the PD filing area. The retention time is minimum 10 years.
- Checklist for licence verification (label), located on the X:Drive (X:\Templates\Others\Parallel Distribution).
- EudraGMP database: EMA public website > Home > About Us > What we do > Telematics programme > EudraGMP.

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3. Instructions

List of abbreviations

EudraGMP	public database offering support for regulatory activities in the area of manufacturing where most of the Manufacturing and Importing Authorisations issued by the EU member states can be found.
MIA	Manufacturing and Importation Authorisation; authorisation issued by the relevant national competent authority of EU member states to authorise manufacture or importation of medicinal products within that member state. Any company undertaking secondary packaging for parallel-distributed medicinal products is required to hold this type of authorisation.
NCA	National competent authority.
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.
WDA	Wholesaler's Distribution Authorisation; authorisation issued by the relevant national competent authority of EU member states to authorise wholesale distribution of medicinal products. Any company undertaking (parallel) distribution of medicinal products is required to hold this type of authorisation.

When submitting a new initial notification, the Pd provides the Agency with a copy of the Wholesaler's Distribution Authorisation and/or Manufacturing Importing Authorisation (hereinafter called 'licence'). Before validating the notification, the PD assessor (Operational initiating agent) checks the validity of the licence and whether the Pd is authorised to perform the activity of parallel distributing and/or repackaging medicinal products.

Therefore, this WIN should be read as a detailed description of step 6 of SOP/INSP/2014: Processing of parallel distribution initial notifications.

Step	Action	Responsibility
When is an (updated) licence required		
1.	• Is this a new Pd or a new repackager in the PD database? If yes, then a licence is required. Go to step 1.1. If no, go to step 2.	PD assessor (Operational initiating agent)
1.1	Verify if the Pd already submitted a licence, by checking the documents in the Eudralink message. If licence was provided, go to step 3. If licence was not provided, continue with step 1.2.	PD assessor (Operational initiating agent)

Step	Action	Responsibility
1.2	Contact Pd, requesting a licence.	PD assessor (Operational initiating agent)
1.3	If licence is received, continue with step 3. If a new licence is not provided within 90 days, the procedure ends unless the Pd confirms that there is a delay. In that case, a new reasonable deadline will be set up and agreed by the EMA.	PD assessor (Operational initiating agent)
2.	• Has the Pd notified the Agency of any change that would necessitate updating the licence (e.g. change in the address or the name of the Pd)? If yes, then an updated licence is required. Go to step 2.1. If no, go to step 3.	PD assessor (Operational initiating agent)
2.1	Contact Pd, requesting an updated licence.	PD assessor (Operational initiating agent)
2.2	If updated licence is received, continue with step 3. If no licence is received, the procedure ends.	PD assessor (Operational initiating agent)
Checking the validity of the licence		
3.	• Is the licence provided in date? If yes, go to step 4. If no, go to step 3.1.	PD assessor (Operational initiating agent)
3.1	Contact Pd, requesting an updated licence.	PD assessor (Operational initiating agent)
3.2	If updated licence is received, continue with step 4. If no licence is received, the procedure ends.	PD assessor (Operational initiating agent)
4.	• Was the licence verification label on the current licence dated more than 5 years ago? If yes, go to step 4.1. If no, go to step 5. Note: all the printed copies of the licences already on file have the label with the checklist for licence verification affixed to the first page.	PD assessor (Operational initiating agent)
4.1	Contact Pd, requesting an updated licence.	PD assessor (Operational initiating agent)

Step	Action	Responsibility
4.2	If updated licence is received, continue with step 5. If no licence is received, the procedure ends.	PD assessor (Operational initiating agent)
5.	• Is the licence a MIA? If yes, go to step 6. If no, go to step 7.	PD assessor (Operational initiating agent)
6.	• Is the pharmaceutical form for which the Pd is applying ticked in the list of authorised pharmaceutical forms in the PD database or is the field 'All dosage forms (secondary repackaging)' in the PD database ticked? If yes, go to step 7. If no, go to step 6.1.	PD assessor (Operational initiating agent)
6.1	Contact Pd, requesting an updated licence covering the relevant pharmaceutical form.	PD assessor (Operational initiating agent)
6.2	If updated licence is received, continue with step 7. If no licence is received, the procedure ends.	PD assessor (Operational initiating agent)
7.	Print one copy if the licence is received electronically. Verify if the licence is complete (no pages missing and, in case of a MIA, if the annexes listing all the authorised pharmaceutical forms are attached). Note: It is recommended to request an English version of the licence; if no English version available, this step can be performed by any Assistant in the Sector/ Unit that speaks the language of the member state that issued the licence.	PD assessor (Operational initiating agent)
8.	Open the EudraGMP database and compare the licence submitted by the Pd with the one in EudraGMP. Check whether the Pd and/or repackager is authorised to perform parallel distribution and/ or repackaging activities. If they are not authorised, the procedure ends. In case the MIA lists "batch certification only", request the Pd to provide the copy of the MIA for the company performing secondary packaging. Note: To this date, EudraGMP lists only MIAs and not WDAs. This is due to change with the full implementation of the Falsified Medicines Directive which stipulates that WDAs will also be included in the current EudraGMP.	PD assessor (Operational initiating agent)
9.	Put a licence verification checklist label on the first page of the	PD assessor

Step	Action	Responsibility
	licence, using template 'Checklist for licence verification (label)' and: • Tick the appropriate box on the checklist for 'Wholesale Distribution' or 'Manufacturing', accordingly. • If it is a MIA, tick the authorised pharmaceutical forms, as listed in the licence or/and EudraGMP. • Sign and date the checklist.	(Operational initiating agent)
Updating the PD database and filing the licence		
10.	Update the PD database with the details of the PD and/or repackager and all other licence-related information. Note: If the same company holds both a WDA and a MIA, create a record in the PD database for each activity.	PD assessor (Operational initiating agent)
11.	File the licence alphabetically and per company in the corresponding licence folders in the PD filing area. Continue with step 7 of SOP/INSP/2014.	PD assessor (Operational initiating agent)