Human Medicines Division
EMA/184143/2024

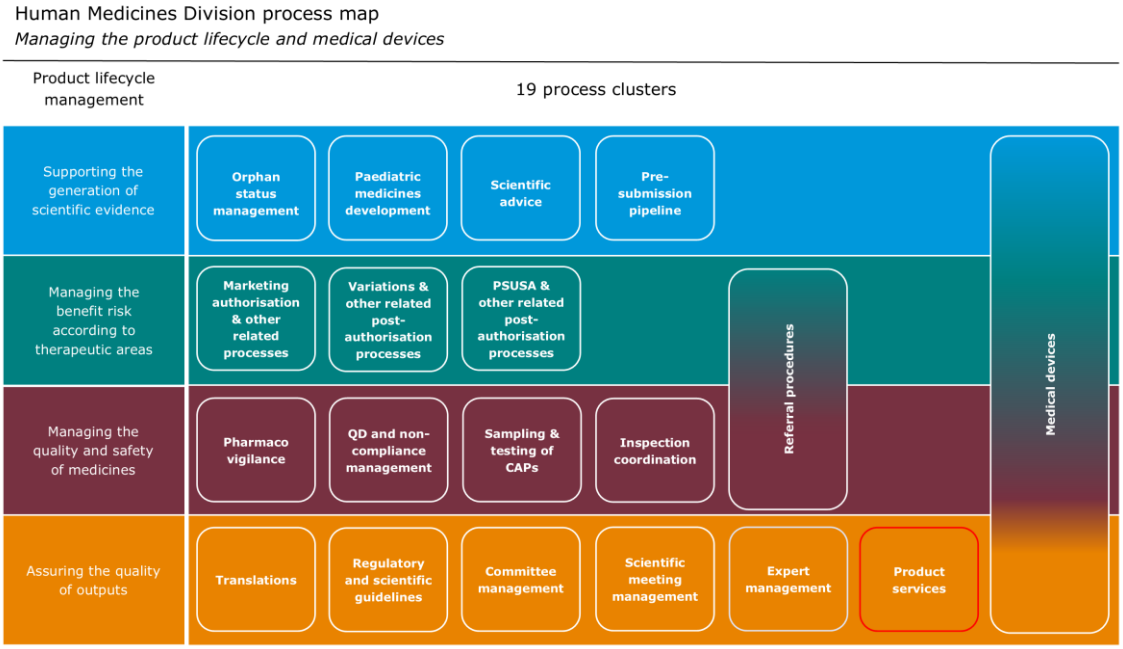
Business process description

Title: Parallel distribution		
Status: **PUBLIC**		Document no.: BPD/H/012a
Author: Process Lead	Approver: Lead Process Manager	Effective date: 25-OCT-24
Name: [On file]	Name: [On file]	Review date: 25-OCT-27
Signature: [On file]	Signature: [On file]	Supersedes: N/A

1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the parallel distribution, which ensures compliance of products distributed in parallel with the conditions laid down in Community legislation. Parallel distribution involves the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing authorisation holder.

The parallel distribution process belongs to the product services process cluster. The product services process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



Parallel distribution process:

It describes the processing of the initial notification, the annual update notification, and the bulk change notification for parallel distribution.

2. Changes since last revision

New business process description

3. Related documents

Guidelines:

- Guideline on the packaging information of medicinal products for human use authorised by the Union
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use

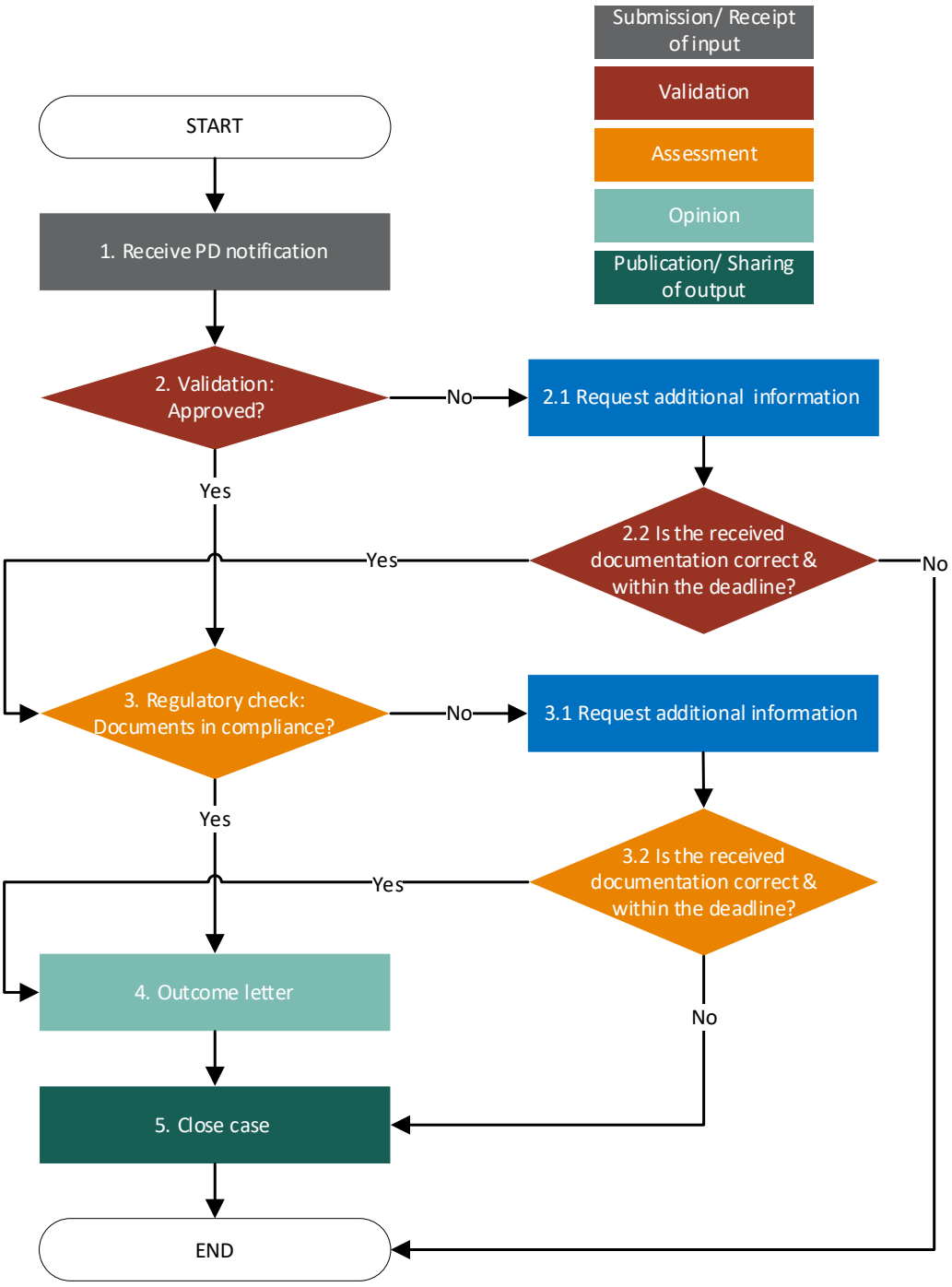
Relevant information:

- Checklist for Annual Updates for Parallel Distribution
- Checklist for Initial Notifications for Parallel Distribution
- Falsified medicines
- Frequently asked questions about parallel distribution
- IRIS guide for applicants
- List of centrally authorised products requiring a notification of a change for update of annexes

4. Abbreviations/Definitions

CAPs	Centrally authorised products
Pd	Parallel distributor
PD	Parallel Distribution
PD notification	Collective term for the initial notification, annual update notification, and bulk notifications (change of name and/or address, change of manufacturer, reassignment of notices for parallel distribution)
PD register	The public register of PD notices, a public register of the Agency's most current list of parallel distributed medicinal products checked to be in compliance with the marketing authorisation and European Union legislation
PSUSA	Periodic safety update report single assessment
QD	Quality defect

5. Process map(s)



Note: Blue colour represents other steps of a process that are not covered by the above legend

6. Procedure

Step	Description
1.	**Receive PD notification** • After receiving the PD notification electronically, assign to the procedure manager
2.	**Validation: Approved?** • If yes, go to step 3 • If no, go to step 2.1
2.1	**Request additional information from Pd** • Email any comments resulting from the validation check to the Pd and inform Pds that they receive one round of comments which they should implement in one go (go to step 2.2)
2.2	**Is the received documentation correct and within the deadline?** • If yes, go to step 3 • If no, the case is invalidated, and the process ends
3.	**Regulatory check: Documents in compliance?** All the documentation should be compliant with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation. • If yes, go to step 4 • If no, go to step 3.1
3.1	**Request additional information from Pd** • Email any comments resulting from the regulatory check to the Pd and inform Pds that they receive one round of comments which they should implement in one go (go to step 3.2)
3.2	**Is the received documentation correct and within the deadline?** • If yes, go to step 4 • If no, go to step 5
4.	**Outcome letter** • Generate the outcome letter
5.	**Close case** Finalise the procedure in the system. Pd will be informed that the procedure has been finalised. • If the procedure has a positive outcome, the outcome letter is made available, and the PD register is automatically updated • If the procedure has a negative outcome, the decision is recorded in the system