



Work instructions

Title: Publication of the monthly and annual overview of Parallel Distribution notices issued by the EMA		
Applies to: Parallel Distribution and Certificates section, Compliance and Inspection sector		
Status: PUBLIC		Document no.: WIN/INSP/2037
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1. Changes since last revision

Major update including revision of the procedure due to the implementation of the new Parallel Distribution database in FileMaker Pro and update to reflect the new organisational names in the Agency and new corporate identity.

2. Records

- The electronic documents for the monthly overview of notices issued by EMA are stored in DREAM under Cabinets/ 01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Statistics/ Statistics 2010 -2019/ 201x /201 x-months.
- The electronic documents for the annual overview of notices issued by EMA are stored in DREAM under Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Statistics/Statistic_annual overview.
- A paper copy of the monthly /annual overview of notices issued is filed for information in the dedicated folders by the co-ordinator of the Parallel Distribution secretariat.



3. Instructions

This WIN describes how to prepare the monthly and annual overview of Parallel Distribution notices issued by the Agency.

Preparation of the monthly overview of notices will start at the beginning of the next month when the notices of the given month are signed by the head of sector. The deadline for giving the document for publication is 10th of the following month.

Step	Action	Responsibility
1.	<ul style="list-style-type: none"> For monthly reports, create a new folder in DREAM: Cabinets/ 01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Statistics/ Statistics 2010 -2019/ 201x /201 x-months. For annual overview, the folder is already created in DREAM: Cabinets/ 01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Statistics/ Statistic annual overview. 	PD assistant
2.	<ul style="list-style-type: none"> For monthly reports, open Filemaker Pro/ Statistics/ Monthly Overview / write the appropriate month and year/click search. For annual overview, open Filemaker Pro/ Statistics/ Monthly Overview / write the appropriate year/click search. 	PD assistant
3.	<ul style="list-style-type: none"> For monthly reports, save the documents as Excel / Initial notices for Parallel Distribution _month _201X in the above mentioned DREAM folder. For annual overview, save the documents as Excel / Statistics_overview_201X in the above mentioned DREAM folder. 	PD assistant
4.	Sort the data in Excel / by Product name, then by Parallel Distributor, then by Date initial notice, delete the last two columns about initial notice month and year.	PD assistant
5.	<ul style="list-style-type: none"> For monthly reports, create a Word document using one from the previous month and rename it to "Initial notices for Parallel Distribution_ month x". For annual overview, create a Word document using one from the previous year and rename it to "Statistic overview_201x". 	PD assistant
6.	To prepare the statistics for the website for the current month/ year, change the month/ year in the title of the document and add the current date.	PD assistant
7.	<ul style="list-style-type: none"> For monthly reports, copy the notifications for which a notice was issued by the EMA in the given month/ year from Initial notices for Parallel Distribution 200X_month Excel/ into the cells of the table of Initial notices for Parallel Distribution_ month_ 201x Word. (Delete duplicate entries if applicable). 	PD assistant

Step	Action	Responsibility
	<ul style="list-style-type: none"> For annual overview, copy the notifications for which a notice was issued by the EMA in the given year from Statistics_overview_201X into the cells of the table of Statistics_overview_201X Word documents. (Delete duplicate entries if applicable). 	
8.	Ensure that the format for publication of documents to be published on the EMA website is applied (font size: Verdana 9 for the table, font: no bold, font colour: black, cell alignment: top and left, and no split information).	PD assistant
9.	Create a PDF rendition of the Word document Initial Notices for Parallel Distribution _month 200X / Statistic Overview_201x and save it in the appropriate DREAM folder (see a screenshot of the PDF file below).	PD assistant
10.	Copy the PDF-file to the G: Drive (G:\External Information Draft\SIGN OFF\Inspections \Parallel Distribution).	PD assistant
11.	Prepare the web content transmission slip using the transmission slip from the previous month/ year: "Transmission slip PD statistics_201X Month / Transmission slip_PD Statistics_overview 201X" saved in DREAM under Cabinets/ 01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Statistics/ Statistics 2010 -2019/ 201x /201 x-months.	PD assistant
12.	Prepare a signature book with the transmission slip and a print-out of Initial Notices for Parallel Distribution _month 200X/ Statistic Overview_201x.	PD assistant
13.	Forward the signature book for sign-off by the required persons (Editorial quality-check, Head of Section/ Sector/ Unit, Press office, External Web Team).	PD assistant
14.	<ul style="list-style-type: none"> For monthly reports, file a paper copy of the monthly overview in the monthly overview folder. For annual overview, file a paper copy of the annual overview in the annual overview folder. 	PD assistant



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 May 2012
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Patient Health Protection

Initial Notices for Parallel Distribution – April 2012

Parallel distributor	Date of notification	Product name	Strength	Pharmaceutical dosage form	Pack size	EU-number	Member State(s) of Origin	Member State(s) of Destination	Date of Notice letter
2 Care 4	21/03/2012	Abilify	1 mg/ml	Oral solution	1 bottle + 1 cup + 1 calibrated dropper	EU/1/04/276/034	Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom	Denmark	24/04/2012
2 Care 4	21/03/2012	Abilify	1 mg/ml	Oral solution	1 bottle + 1 cup + 1 calibrated dropper	EU/1/04/276/034	Austria, Belgium, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, The Netherlands, United Kingdom	Sweden	24/04/2012
AMIMED DIRECT LTD	25/04/2012	Abilify	1 mg/ml	Oral solution	1 bottle + 1 cup + 1 calibrated dropper	EU/1/04/276/034	Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom	Ireland, United Kingdom	26/04/2012
Docpharm GmbH&CoKGaA	03/04/2012	Abilify	30 mg	Tablet	28 x 1	EU/1/04/276/017	Austria, Belgium, Denmark, Finland, France, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Spain, Sweden, The Netherlands, United Kingdom	Germany	25/04/2012

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