EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Work instructions

| Title: Product information for parallel distributors | | |
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| Applies to: P-CI-PDC | | |
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## 1. Changes since last revision

Full revision of the WIN to include provision of the product information of centrally authorised medicinal products to parallel distributors both pro-actively after an update of the product information and upon individual request of a parallel distributor.

A new step has been added since a process improvement took place and the annual update was introduced. Except in those cases for which the EMA has specifically indicated the need for submitting a notification of a change[1] (as explained in section 3.2.), parallel distributors are no longer required to submit such a change to the Agency following updates in the annexes of a marketing authorisation. It is their responsibility to update the product information in accordance with the latest annexes. In addition, once a year they are required to submit an annual update including all scopes of changes occurring to the product.

[1] Medicinal products for which a safety variation has obtained a CHMP positive opinion as indicated in the CHMP meeting reports. We prepare a monthly summary for Parallel distributors; this list is also published on our website.

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## 2. Records

The list with the latest version of product information with the updated annexes can be found in DREAM under Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Latest Annexes/201x-201x.

The list with the latest version of product information with the products which require notification of a change can be found in DREAM under: Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Products with required submission/published pdfs. This list is also published on the European Medicines Agency public website under Home/ Regulatory/ Human Medicines/ Parallel distribution/ Guidance / Guidance Documents / Guidance on centrally authorised products requiring a notification of a change for update of annexes.

Community Register of Medicinal Products for human use can be found on the European Commission website: European Commission /Public health /Reference documents /Register /Human.

European public assessment reports are located on the European Medicines Agency public website: Home/ Find medicines/ Human Medicines.

The individual requests for product information are accessible in the functional Parallel Distribution e-mail box (paralleldistribution@ema.europa.eu): Public Folders\All Public Folders\Chrono in\Workflow\Parallel Distribution.

The following templates can be found on the X drive:

- Template 1: E-mail for sending product information pro- actively to the parallel distributors (X:\Templates\Others\Parallel Distribution\Template for the e-mail to the parallel distributors)
- Template 2: E-mail for sending product information upon request from the parallel distributors (X:\Templates\Others\Parallel Distribution\Template for the e-mail to the Pd_request)

## 3. Instructions

### *List of abbreviations*

| | |
|---|---|
| CHMP | Committee for Medicinal Products for Human Use |
| DREAM | Document Records Electronic Archive Management system |
| EPAR | European public assessment report |
| MAH | Marketing Authorisation Holder |
| P-CI-PDC | Parallel Distribution and Certificates section in the Compliance and Inspection sector 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 |

SIAMED Sistema de Información Automatizada sobre Medicamentos, which is a model system for computer-assisted drug registration that enables the EMA to track its core processes and retrieve key registration data

This WIN describes how to provide parallel distributors with the latest product information related to the latest annexes to the marketing authorisation of centrally authorised products. This information is pro-actively provided on a monthly basis by the designated PD assessor. This WIN also explains how to handle individual requests of latest product information from parallel distributors.

Moreover, the designated PD assessor updates on a monthly basis the list of products for which a CHMP positive opinion has been issued for a safety variation.

## *3.1. Product information concerning the latest annexes*

### 3.1.1. Pro-actively sending of Product Information

1. Request a report of the latest finalised/approved variations in post authorisation from the SIAMED administrator in Excel format. Date range is first day of the given month until the last day of the given month.
2. Rename the Excel "Updated Annexes_ Month_Year", open it and sort them by status.
3. Delete all the pending and rejected variations.
4. Sort by trade name and delete duplicates of variations, if any, for the same product.
5. Go to the European Medicines Agency and the European Commission website and double-check whether the annexes have been published for each product. Move the ones whose annexes are not yet published on the websites to another Excel spread sheet and save it on your desktop. Next month, open this Excel from the desktop and check again whether for those variations there is any update on these websites. In case the new annexes are published on any of these websites, copy them to the actual "updated annexes" document.
6. Delete the following columns: application type, application status, outcome status and decision. Merge the date of the EC decision and Opinion/Notification date. Rename the files and arrange columns in the following order: "Domain", "Product Name", "Application Number", "EU Numbers (Affected by Application)", "Annexes Affected (List)", "Revision date" and "Public Scope".
7. Cross-check the "Public Scope" field for each product in Excel against the scope of change in SIAMED as part of the information is lost during the extraction of the Excel files. If so, go to SIAMED, type the product name, search for the relevant variation and complete the text in the Excel sheet.
8. Ensure that the format follows the Agency style (font: Verdana 9, regular, font colour: black,) and highlight the IIIA and IIIB documents which give information to Pd-s about the changes affecting the labelling and package leaflet.
9. Prepare the e-mail message to the Pd-s (see template 1 on X: drive), and attach the updated product information from L: drive.
10. Copy the e-mail addresses of all parallel distributors from the PD database.
11. Send the message in Bcc to the pd-s with a copy to the PD assessors.

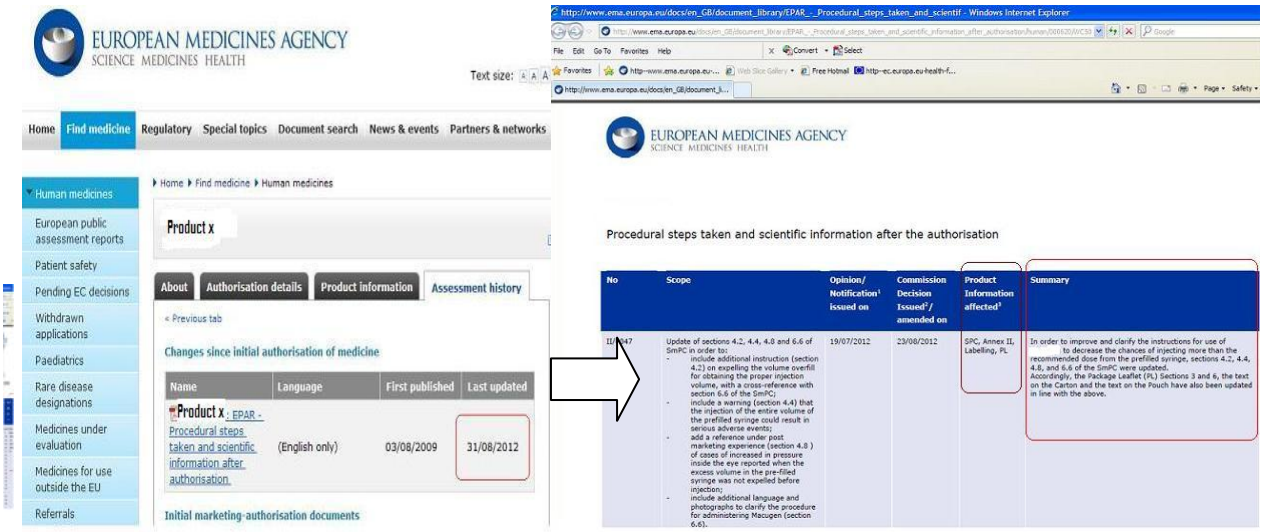
12. Save the e-mail and updated document in DREAM Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Latest Annexes/201x-201x.

### 3.1.2. Individual requests for the latest version of Product Information

1. Receive an individual request from a parallel distributor via the PD functional e-mail box (paralleldistribution@ema.europa.eu) or via a personal e-mail.
2. Find the latest version of the product information on either the European Medicines Agency or the European Commission website.
3. Save the latest version of the product information in the concerned EU language(s) (preferably in PDF format) on the L: drive and create a zip file, if necessary.
4. Prepare the e-mail message to the Pd (see template 2 on X: drive) and attach the latest version of the product information from the L: drive.
5. Tick the original e-mail with the request in the functional PD e-mail box.

## *3.2. Product information requiring notification of a change*

1. After the CHMP meeting every month, check the meeting highlights on the EMA external website: Home /About Us/ Committees/ CHMP/ Committee meeting reports.
2. From the latest report page, print out the "**Opinions on safety variations"** pdf file and write the product names and month of adoption of such opinions into the "*product list with safety updates"* Excel file hereinafter referred as "excel". This "excel" is located in DREAM Cabinets/01. Evaluation of Medicine/Parallel Distribution/Human Medicines/Products with required submission.
3. Check for each of the products in the "excel" whether their annexes (labelling and package leaflet) has been updated in EPAR/ Assessment history[2], and if the scope has been updated with the scope of the "Opinions on safety variations" (see screenshot below):




[2] In case the annex is not updated (e.g. there is a delay between a positive opinion and the EPAR update), check European Commission website and if it is updated there, go to Siamed to check scope and use information from Siamed.

4. If the product annexes has been updated, copy the product name, summary, variation number, date of the concerned annex and EU number into the "*Guidance on centrally authorised products requiring a notification of a change for update of annexes"* Word document hereinafter referred as "word". This is located in the same DREAM folder as the "excel" and contains the list of products from the previous months.
5. Write the publishing date into the "Date of communication" column and after the rationale, write the latest annex date and variation numbers which the Pd need to use for updating their PL and labelling.
6. Highlight the updated products in grey colour in the "excel" document.
7. Check the "word", update the existing products if they have new annexes including the safety variation and other major changes (information could be found on the EPAR assessment history tab as explained in point 3.2.3), and update the date and variation number. Finally, remove from the list those products which have been there for more than 6 months.
8. Highlight the new products in the list: go to *References/Insert Index/Mark entry/Mark.*
9. Scroll down to *Index,* highlight the products there and click *Update field*.
10. Check in the "word" to DREAM.
11. Convert the "word" to pdf file and save it also in DREAM.
12. Save the pdf on G:\External Information Draft\SIGN OFF\Inspections\Parallel Distribution together with the transmission slip.
13. Print the pdf and the transmission slip and forward the signature book for sign-off by the required persons (Editorial quality-check, Head of Section/ Sector, Press office, External Web Team).
14. When the document is published on the website, attach the updated product information to the above referred e-mail (product information to the parallel distributors located on X: drive - template 1).