EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

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IRIS guide to the platform for parallel distribution industry users
Version 1.0

Purpose and context

This guide has been produced to help individuals using the IRIS | Regulatory & Scientific Information Management platform understand how to use the platform to submit a notification for parallel distribution.

This document is intended for **Industry users** who have already been granted Industry user access roles for the IRIS portal.

If you have not yet requested a user access role or have not carried out the pre-requisite steps please refer to the '**IRIS Guide for Registration**' which can be found under 'Guidance' in the parallel distribution guidance section of the EMA corporate website.

1. How to create an initial notification for parallel distribution

In order to create a notification for parallel distribution in the IRIS portal, you must have already registered for, and been granted an '**Industry Manager**' role through the EMA Account Management portal.

Creating a new notification for parallel distribution is the most involved process that you will carry out using the IRIS portal.

1. From the IRIS portal home page, click on "**My submissions**";

2. Click on "**Draft submissions**";

3. Click "**New draft**" [a screen with the heading "Portal – New Submission" opens up showing 3 stages. The first stage "**1. Choose Applicant Type**" is highlighted in blue];

4. From the drop-down arrow on the box below "**Is the applicant an organisation or individual?***" (marked with a red asterisk "*****") select "**Organisation**" and click "**Next**" ;

5. "**2. Choose Submission Type**" is now coloured blue and 4 mandatory fields appear labelled "**Organisation**" "**Location**", "**Submission Type**" and "Manager";

6. Use the **magnifying glass search symbol** to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the user role that you logged into the portal as will be displayed here).

7. Pick the right organisation (there may only be one) and click "**Select**";

8. Use the search symbol to look up the locations available for you to select, pick the right one and click "**Select**";

9. Use the search symbol to look up the submission types available, click on "**Initial Notification for Parallel Distribution**" and "**Select**";

10. Use the search symbol to look up the affiliated managers available for you to select, pick the one who will be managing this submission and click "**Select"** Click "**Create and Next**";

11. Click "**Add**" and then magnifying glass search symbol to bring up a list of people to select as contributors (N.B. The list will only include those people who have been granted an Industry access role that is affiliated to the specific organisation (Company + Country) you selected in the previous screen. If no-one has done this, the list will be empty);

12. If there are names on the list, select one or more contributors and their names will appear on the main "Portal – New Submission" screen (N.B. You are not required to add any contributors. You can also add and remove contributors later on);

13. Click "**Continue to submission form**". On the upper right hand side of the "Portal – New Submission" screen a reference number (e.g. EMA/PD/0000001234) and the procedure type of your draft submission is displayed. (N.B. It is a good idea to take note of the reference number created). There is also now a list of eight steps relating to the notification of parallel distribution displayed on the left hand side of your screen, each of which will be followed by a 'green tick' once completed;

14. Click on "**Parallel Distributor Information**" to bring up a screen on which to enter a Purchase Order number or a Reference number defined by you which will be quoted on the invoice. Then add your SAP customer number then click on 'save and return';

15. Now click on "**Details of Centrally Authorised Product**" and click on the **magnifying glass search symbol** to bring up the entire catalogue of centrally authorised products. Search for the relevant product and presentation which you intend to distribute and **"Select";**

16. Indicate whether the pack size has been changed and if yes, search for the product presentation being sourced by clicking on "Add". Then click **"Save and Return"** to return to the front page of the Submission Form;

17. Click on "**Member States of Origin and Destination**" to indicate the MSO(s) and MSD(s) by clicking "**Add**" in each category and selecting;

18. Select **"Yes"** or **"No"** as applicable for the Specific Mechanism. If "Yes", the "**Date of prior notification**" has to be populated with a date. Then click "**Save and Return**";

19. Click on "**Details of Repackagers**" and search for the relevant organisation(s) by clicking **"Add"**. If the desired organisation does not appear, the manufacturing and importation authorisation number should be added in the field provided below. Click "**Save and Return**";

20. Back in the main "**Submission Form**" screen, click on "**Nature of Repackaging**";

21. In the next screen that appears, the first question will default to "Yes", as this will always apply to an initial notification for parallel distribution;

22. Indicate the repackaging nature chosen, but ticking "relabelling", "reboxing", or "relabelling and reboxing". Details can be provided in the field below;

23. The "Date of the latest product information update" (annex) used should be indicated. Then click "Save and Return";

24. Back in the main "**Submission Form**" screen, click on "**Documents**";

25. Click on the blue "**Upload Documents to EMA**" button near the top of the screen;

26. The pop-up window* that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA;

Note: In order for the above step to work, you must have "allowed pop-up windows" in your browser. If nothing happens, one way to adjust your web browser settings is to look for a little icon at the right hand end of your web browser search bar with a little red cross next to it click on this and agree to allow pop-ups windows.

27. **Drag and drop** or use **"Upload"** button to add the relevant document(s) into the folder and close the pop-up window by clicking on the cross ("x") in the top right hand corner;

28. Confirm that the listed documents have been provided and click "Save and Return";

29. You have now successfully created a draft submission which will now appear in your "**Draft Submissions**" list and can open it up again to add more information when you are ready to do so;

30. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;

31. Click on the downward arrow on the right hand side and select "**Edit Draft**" from the drop-down list that appears;

32. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;

33. Repeat steps "29." to "30." until you are ready for final submission;

34. When you are ready to submit your final application, click on "Declaration" and tick all the boxes;

35. Next click on **"Submit Application, click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm…") to formally declare that you are authorised to submit the application; Click on the "**Declaration and submission**" button;

36. If you are unsure or think of any part of the application you want to revise, click "**Review Application**" and this will return you to the draft submission;

37. If you are sure you want to submit the application, click "**Submit**".

Your application has now been submitted and is locked for edit unless EMA open it up again for you to add or amend any information.

You are returned to the portal homepage and you can now look up the submission you have just submitted using the "My Submission" drop-down menu at the top of the page and selecting either "Draft Submissions" or "Ongoing Submissions".

2. How to create a safety update

1. From the IRIS portal home page, click on "**Draft submissions**";

2. Click "**New draft**" [a screen with the heading "Portal – New Submissions" opens up showing 3 stages. The first stage "**1. Choose Applicant Type**" is highlighted in blue];

3. From the drop-down arrow on the box below "**Is the applicant an organisation or individual?***" select "**Organisation**" and click "**Next**" ;

4. "**2. Choose Submission Type**" is now coloured blue and 4 mandatory fields (marked with a red asterisk "*") appear labelled "**Organisation**" "**Location**" "**Submission Type**" and "**Manager**"

5. Use the **magnifying glass search symbol** to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the user role that you logged into the portal as will be displayed here).

6. Pick the right organisation (there may only be one) and click "Select";

7. Use the search symbol to look up the locations available for you to select, pick the right one and click "**Select**";

8. Use the search symbol to look up the submission types available, click on "Safety Update" and "**Select**";

9. Use the search symbol to look up the affiliated managers available for you to select, pick the one who will be managing this submission and click "**Select**";

10. Click "**Create and Next**";

11. Click "**Add**" to bring up a list of people to select as contributors (N.B. The list will only include those people who have been granted an Industry access role that is affiliated to the specific organisation (Company + Country) you selected in the previous screen. If no-one has done this, the list will be empty);

12. If there are names on the list, select one or more contributors and their names will appear on the main "Portal – New Submission" screen (N.B. You are not required to add any contributors. You can also add and remove contributors later on);

13. Click "**Continue to submission form**". On the upper right hand side of the "Portal – New Submission" screen a reference number (e.g. EMA/PD/0000001234) and the procedure type of your draft submission is displayed. (N.B. It is a good idea to take note of the reference number created). There is also now a list of eight steps relating to the notification of parallel distribution displayed on the left hand side of your screen, each of which will be followed by a 'green tick' once completed;

14. Click on "**Details of the Parallel Distribution Notices**" to bring up a screen on which you can select the notices for which the safety update will be submitted;

15. Back in the main "**Submission Form**" screen, click on "**Documents**";

16. Click on the blue "**Upload Documents to EMA**" button near the top of the screen;

17. The pop-up window* that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA;

*Note: In order for the above step to work, you must have "allowed pop-up windows" in your browser. If nothing happens, one way to adjust your web browser settings is to look for a little icon at the right

hand end of your web browser search bar with a little red cross next to it click on this and agree to allow pop-ups windows.

18. Drag and drop or use **"Upload"** button to add the relevant document(s) into the folder and close the pop-up window by clicking on the cross ("x") in the top right hand corner;

19. Confirm that the listed documents have been provided;

20. Confirm whether a Text Comparison Report has been provided and click "**Save and Return**";

21. You have now successfully created a draft submission which will now appear in your "**Draft Submissions**" list and can open it up again to add more information when you are ready to do so;

22. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;

23. Click on the downward arrow on the right hand side and select "**Edit Draft**" from the drop-down list that appears;

24. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;

25. Repeat steps "21." to "22." until you are ready for final submission;

26. When you are ready to submit your final application, click on "**Declaration**";

27. Click on the tick boxes to the left of the declaration statements to confirm all three statements and click "**Save and Return**";

28. Click on the "**Submit Application**" button;

29. Tick the box to the left of the screen to confirm the declaration and then click "**Declaration and Submission**";

30. If you are unsure or think of any part of the application you want to revise, click "**Review Application**" in the pop up box and this will return you to the draft submission;

31. If you are sure you want to submit the application, click "**Submit**".

3. How to create an Update Parallel Distribution Notice Status

1. From the IRIS portal home page, click on "**Draft submissions**";

2. Click "**New draft**" [a screen with the heading "Portal – New Submissions" opens up showing 3 stages. The first stage "**1. Choose Applicant Type**" is highlighted in blue];

3. From the drop-down arrow on the box below "**Is the applicant an organisation or individual?***" select "**Organisation**" and click "**Next**" ;

4. "**2. Choose Submission Type**" is now coloured blue and 4 mandatory fields (marked with a red asterisk "*") appear labelled "**Organisation**" "Location" "**Submission Type**" and "**Manager**";

5. Use the **magnifying glass search symbol** to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the user role that you logged into the portal as will be displayed here).

6. Pick the right organisation (there may only be one) and click "**Select**";

7. Use the search symbol to look up the locations available for you to select, pick the right one and click "**Select**";

8. Use the search symbol to look up the submission types available, click on "**Update Parallel Distribution Notice Status**" and "**Select**";

9. Use the search symbol to look up the affiliated managers available for you to select, pick the one who will be managing this submission and click "**Select**";

10. Click "**Create and Next**";

11. Click "**Add**" to bring up a list of people to select as contributors (N.B. The list will only include those people who have been granted an Industry access role that is affiliated to the specific organisation (Company + Country) you selected in the previous screen. If no-one has done this, the list will be empty);

12. If there are names on the list, select one or more contributors and their names will appear on the main "Portal – New Submission" screen (N.B. You are not required to add any contributors. You can also add and remove contributors later on.);

13. Click "**Continue to submission form**". On the upper right hand side of the "Portal – New Submission" screen a reference number (e.g. EMA/PD/0000001234) and the procedure type of your draft submission is displayed. (N.B. It is a good idea to take note of the reference number created). There is also now a list of eight steps relating to the notification of parallel distribution displayed on the left hand side of your screen, each of which will be followed by a 'green tick' once completed;

14. Click on "**Details of the Parallel Distribution Notices**" to bring up a screen on which you can select the notices for which the status will be updated;

15. Return to the "**Submission Form** and click on "Parallel Distribution Notice Status" to select the status of the notices to make them dormant or to withdraw the notices.

16. Back in the main "**Submission Form**" screen, click on "Documents";

17. Click on the blue "**Upload Documents to EMA**" button near the top of the screen;

18. The pop-up window* that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA;

*Note: In order for the above step to work, you must have "allowed pop-up windows" in your browser. If nothing happens, one way to adjust your web browser settings is to look for a little icon at the right hand end of your web browser search bar with a little red cross next to it click on this and agree to allow pop-ups windows.

19. Drag and drop or use **"Upload"** button to add any relevant document(s) into the folder and close the pop-up window by clicking on the cross ("x") in the top right hand corner;

20. Confirm that any necessary documents have been provided;

21. You have now successfully created a draft submission which will now appear in your "Draft Submissions" list and can open it up again to add more information when you are ready to do so;

22. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;

23. Click on the downward arrow on the right hand side and select "**Edit Draft**" from the drop-down list that appears;

24. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;

25. Repeat steps "22." to "23." until you are ready for final submission;

26. When you are ready to submit your final application, click on "Declaration";

27. Click on the tick boxes to the left of the declaration statements to confirm all three statements and click "**Save and Return**";

28. Click on the "**Submit Application**" button;

29. Tick the box to the left of the screen to confirm the declaration and then click "**Declaration and Submission**";

30. If you are unsure or think of any part of the application you want to revise, click "**Review Application**" in the pop up box and this will return you to the draft submission;

31. If you are sure you want to submit the application, click "**Submit**".

4. How to add contributors to a draft PD notification

You can only do this for the draft applications that you yourself have created as an "Industry Manger".

From the IRIS portal home page, carry out the following steps:

1. Click on "**My submissions**" then "**Draft submissions**";

2. Scroll down and find the application you want from the list of your drafts;

3. On the right hand side, click on the drop-down arrow and select "**Manage Contributors**";

4. Click "**Add**";

5. In the pop-up window, click the **magnifying glass search symbol** to bring up a list (of people eligible to be contributors) search by name and find the name you want to add as a contributor;

6. Click "**Continue to submission form**";

7. To add more contributors to the same application, repeat steps 4. to 6. above.

5. How to delete a draft application

You can only do this for the draft applications that you yourself have created as an "Industry Manger" role.

1. Click on "**My submissions**" then "**Draft submissions**";

2. Scroll down and find the application you want from the list of your drafts;

3. On the right hand side, click on the drop-down arrow and select "**Delete Draft**" and a confirmation message will open up in a new window;

4. Click on the "**Delete**" button to confirm that you definitely want to delete your draft – you cannot undo this afterwards;

5. The draft has now been deleted from the portal.

6. How to display and sort submissions

1. From the IRIS portal home page, click on "**My submissions**";

2. Click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";

3. If you have a Manager role, you will see all the submissions you have created and all the submissions you have been assigned to as a contributor. If you have a Contributor role, you will see all the Submissions to which you have been assigned. If you have both roles, you will see all submissions of your own and those for which you have been added as a Contributor;

4. Click on any of the column headings that appear in **blue** font and the rows listed in the table will be sorted either in ascending or descending order – the sorting will be either alphabetical or numerical, depending on the contents of the column.

7. How to search for submissions

1. From the IRIS portal home page, click on "**My submissions**";

2. Click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";

3. If you have a Manager role, you will see all the submissions you have created and all the submissions you have been assigned to as a contributor. If you have a Contributor role, you will see all the Submissions to which you have been assigned. If you have both roles, you will see all submissions of your own and those for which you have been added as a Contributor;

4. In the search bar, you can enter any combination of letters and or numbers that will identify the submission you are looking for and might be contained in the columns that are displayed on screen (e.g. "Submission ID", "Organisation", "Submission Type");

5. If you don't know the exact wording of the submission you are searching for but you know part of it, you can use the asterisk symbol "*" as a 'wild card' to enlarge your search;

6. Click on the **magnifying glass search symbol** or press "Enter" on your keyboard to launch the search;

7. A list of the relevant results that match the search criterion you typed in the search bar will be displayed. If the list contains multiple records, it can be sorted by clicking on the blue column headers, as described in the previous section.

8. How to respond to a notification email from EMA requesting VSI

On receipt of a notification email from EMA stating that "Validation Supplementary Information (VSI)" relating to one of your Ongoing Submissions is required, log into the IRIS portal and carry out the following steps:

1. From the IRIS portal home page, click on "**My submissions**";

2. Click on "**Ongoing submissions**";

3. Locate the submission mentioned in the e-mail by using the sort or search features described in Sections 3.6 and 3.7 earlier in this Guide, or by just scrolling down the list until you find it;

4. At the end of the row in the list where your submission appears, click on the drop-down arrow and select "**View/edit**";

5. In the "**Submission Form**" page that appears click on the sections that you need to update as stated in the notification you received from EMA (e.g.: General Information, Scientific information, etc.);

6. The selected sections will open in edit mode - make the requested modifications and click on "**Save and Return**" - all modifications will have been saved and you will return to the "**Submission Form**" page;

7. If you need to upload documents, click on "**Documents**" and then on "**Upload Documents**" and drag and drop the document(s) into the pop-up window that appears;

8. Click on "**Upload**" (button with an arrow going up) - the documents are now uploaded in the document folder;

9. Close the document folder window by clicking on the "**X**" symbol in the top right corner;

10. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm…") to formally declare that you are authorised to submit this request;

11. Click on the "**Declaration and submission**" button;

12. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click "**Back To List**" and this will return you to the draft submission;

13. If you are sure you want to submit the application, click "**Submit**", then "Ok" and then "**Submit**";

14. Your updated application has now been submitted and will now appear in your "Draft Submissions" list.