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Information Management Division

IRIS guide for Parallel Distribution applicants

Purpose and context

This guide has been produced to help individuals using the IRIS | Regulatory & Scientific Information Management platform understand how to use the portal 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 to Registration**' which can be found on the [IRIS 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 "**Draft submissions**";
2. Click "**Create new submission**" [a screen with the heading "New Draft Submission" 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 "**Are you applying as an individual or on behalf of an organisation**"* (marked with a red asterisk "*") select "**Organisation**" and click "**Next**";
4. "**2. Choose Submission Type**" is now coloured blue and 4 mandatory fields appear labelled "" **Select the organisation on behalf of which you are applying**", "**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**"; If there is more than one location visible, please select the location listed in your Wholesale Distribution Licence and request de-activation of other locations by logging to your OMS account.
8. Use the search symbol to look up the submission types available, click on "**Initial Notification for Parallel Distribution**" and "**Select**";
9. Use the search symbol to look up the affiliated managers available for you to select, pick at least two managers who will have rights to manage this submission and click "**Select**". Click "**Create and Next**";
10. To choose contributors 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);
11. If there are names on the list, select one or more contributors and their names will appear on the main "New Draft Submission" screen (N.B. You are not required to add any contributors. You can also add and remove contributors later on);
12. Click "**Continue to submission form**". On the upper right-hand side of the "Submission Form" 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 steps relating to the initial 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;
13. 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**";
14. 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**";
15. Indicate whether the pack size has been changed (sourced pack size is different from the distributed pack size) 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;
16. Click on "**Member States of Origin and Destination**" to indicate the MSO(s) and MSD(s) by clicking "**Add**" in each category;
17. Select "**Yes**" or "**No**" as applicable for the Specific Mechanism. If "Yes", the "**Date of prior notification**" has to be populated with a date. If "No", please fill in the section "**Please justify why the 'Specific Mechanism' is not applicable to this notification.**" Then click "**Save and Return**";
18. Click on "**Details of Repackagers**" and search for the relevant organisation(s) by clicking "**Add**". The manufacturing and import authorisation number(s) should be added in the field provided below. Click "**Save and Return**";
19. Back in the main "Submission Form" screen, click on "**Nature of Repackaging**";

20. 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;
21. Indicate the repackaging nature chosen, but ticking "relabelling", "reboxing", or "relabelling and reboxing". Details can be provided in the field below;
22. The "Date of the latest product information update" (annex used) should be indicated. Then click "**Save and Return**";
23. Back in the main "Submission Form" screen, click on "**Documents from Industry**";
24. Click on the blue "**Add files**" to upload the documents;
25. 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.*

26. Use "**Upload**" button to add the relevant document(s);
27. Confirm that the listed documents have been provided and click "**Save and Return**";
28. 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;
29. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" and find the draft submission you want to edit;
30. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list that appears;
31. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
32. Repeat steps "29." to "30." until you are ready for final submission;
33. When you are ready to submit your final application, click on "**Declaration**" and confirm all the statements; click "**Save and Return**";
34. Next click on "**Submit Application**", confirm the declaration statement to formally declare that you are authorised to submit the application; Click on the "**Declaration and submission**" button;
35. 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;
36. 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 opens it up again for you to add or amend any information.

You are returned to the "Ongoing Submissions" page and you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Draft submissions and submissions already reviewed by the Agency can be found in "Draft Submissions" and "Completed Submissions" respectively.

2. How to create a safety update

1. From the IRIS portal home page, click on "**Draft submissions**";
2. Click "**Create new submission**" [a screen with the heading "New Draft Submission" 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 "**Are you applying as an individual or on behalf of an organisation?***" 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 "**Select the organisation on behalf of which you are applying**", "**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**"; If there is more than one location visible, please select the location listed in your Wholesale Distribution Licence and request de-activation of other locations by logging to your OMS account.
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 at least two managers who will have rights to manage this submission and click "**Select**", then "**Create and Next**";
10. To add contributors, 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);
11. If there are names on the list, select one or more contributors and their names will appear on the main "New Draft Submission" screen (N.B. You are not required to add any contributors. You can also add and remove contributors later on);
12. Click "**Continue to submission form**". On the upper right-hand side of the "Submission Form" 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 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;
13. Click on "**Details of the Parallel Distribution Notices**" to bring up a screen on which you can select the notices/ regulatory entitlements for which the safety update will be submitted;
14. Back in the main "**Submission Form**" screen, click on "**Documents from industry**";
15. Click on the blue "**Add files**" to upload documents;

16. 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.*

17. Add the relevant document(s) into the folder;
18. Confirm that the listed documents have been provided; confirm whether a Text Comparison Report has been provided; provide the product information used date(annex date), then **"Save and return"**.
19. 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;
20. When you want to add more information, click on **"My submissions"**; then **"Draft submissions"** find the draft submission you want to edit;
21. Click on the downward arrow on the right-hand side and select **"Edit Draft"** from the drop-down list that appears;
22. Make your changes or additions and, if you are still not ready to submit the final application, click **"Return"** to save your draft application;
23. Repeat steps "21." to "22." until you are ready for final submission;
24. When you are ready to submit your final application, click on **"Declaration"**;
25. Click on the tick boxes to the left of the declaration statements to confirm all statements and click **"Save and Return"**;
26. Click on the **"Submit Application"**;
27. Confirm the declaration and then click **"Declaration and Submission"**;
28. 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;
29. If you are sure you want to submit the application, click **"Submit"**.

3. How to create an Annual Update for parallel distribution

The way you do this in IRIS is by following a reasonably simple 'generic submission' process first two stages of which (covered in steps '1.' to '8.' below) are identical to those you follow when creating an initial notification or safety update.

1. From the IRIS portal home page, click on **"Draft submissions"**;
2. Click **"Create new submission"** [a screen with the heading "New Draft Submission" 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 **"Are you applying as an individual or on behalf of an organisation"*** 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 **"Select the organisation on behalf of which you are applying"**, **"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 portal user role that you logged into the portal as will be displayed here).
6. Click on the **right** organisation and (there may only be one) and then click **"Select"**;
7. Use the search symbol to look up the locations available for you to select, click on the **right** location and then click **"Select"**; If there is more than one location visible, please select the location listed in your Wholesale Distribution Licence and request de-activation of other locations by logging to your OMS account.
8. Use the search symbol to look up the submission types available, click on **"Annual Update"** and then click **"Select"**;
9. Use the search symbol to look up managers associated with the selected organisation, pick at least two managers who will have rights to manage this submission and click **"Select"** Click **"Create and Next"**;
10. You are now directed to the third section **"Add Contributors"**;
11. Use the add button to look up users associated with your organisation which you would like to add to this submission as a contributor, use the search symbol and click add once a user has been identified;
12. Click **"Continue to submission form"** and a reference number (e.g. EMA/PD/0000001234) for your draft submission is displayed on the upper right-hand side of the "Submission Form" screen (N.B. It is a good idea to take note of the reference number created)
13. Click on **"Parallel Distributor Information"** to provide financial information "Purchase Order or Reference Number" and "Customer Account Number" of your organisation, then click **"Save and Return"**;
14. Click on **"Details of the Parallel Distribution Notices"** and search for the Product name, Pharmaceutical Form and Member State of destination in order to identify the Regulatory Entitlements for which you wish to submit this annual update. N.B. If there are more than one member of destination country, it is enough to choose just one. Click **"Select all notices"** to display the list of related submissions.
15. Click "Yes" or "No" in the field "Are you informing the EMA of any changes to the selected notices?", then click **"Return"**;
16. In the **"Documents from Industry"** folder please confirm as necessary the upload of documents and provision of a text comparison report, and indicate the date of the annex which has been used for this annual update, then click **"Save and return"**;
17. The **"Documents from EMA"** folder is empty at this stage but will contain documents provided by EMA during the process;
18. Click on **"Declaration"** and tick all boxes to confirm statements accordingly, then **"Save and return"**;
19. If you have **no changes** to report or the only scope of change is update of the product information in line with annex, please **"Submit Application"** at this stage;

20. If you are **reporting changes** to any of the presentations included in this annual update, please **"Return"** to the draft submissions overview at this point (noting down the procedure number may be useful);

4. Notifying scopes of changes in an annual update

1. Back in the Draft Submissions, Click on **"Create new submission"** and then go through steps 2-12, choosing **"Annual Update – Scope of Change"** as the submission type;
2. Click **"Continue to submission form"** and a reference number (e.g. EMA/PD/0000001234) for your draft submission is displayed on the upper right-hand side of the "Submission Form" screen (N.B. It is a good idea to take note of the reference number created);
3. Click on **"Related Submissions (Annual Update only)"** and using the magnifying glass, select the annual update which you left in the draft status before, then **"Save and Return"**;
4. Click on **"Details of the Parallel Distribution Notices"** and search/select the Regulatory Entitlements for which you wish to notify the changes, **"Save and Return"**, as before the Regulatory entitlements should be grouped by scopes of change;
5. Open the scope of change for which you have a change to report, fill in the relevant fields, **"Save and Return"**;
6. To submit this annual update with these changes or to notify about a further set of changes to other Regulatory Entitlements within the annual update, **"Return"** to the **"Draft Submissions"** overview;
7. If you need to add another "Annual Update – Scopes of change entry", click on the drop down arrow to the right of the draft **"Annual Update – Scopes of changes"** and choose **"Clone submission"** in order to create an **"Annual Update – Scopes of changes"** with the exact company information (this allows you to skip the first couple of steps within the submission forms);
8. Click on the drop-down arrow to the right of this cloned draft and select **"Edit"** in order to input the relevant information as per steps 3 – 6;
9. In order to submit the annual update with Annual update - scopes of change linked to it, go back to **"Draft Submissions"**, select the annual update you previously left in draft, click on the drop down arrow to the right, and go to **"Edit draft"**;
10. In the **"Submission Form"** of your annual update you will find a list of related submissions at the bottom of the page which are the "Annual update - scopes of change" related to this annual update;
11. To proceed with the submission, click on **"Submit application"** and tick relevant statement(s), then click **"Declaration and submission"**, then **"Submit"**;

5. How to create an update of parallel distribution notice status

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

2. Click "**Create new submission**" [a screen with the heading "New Draft Submission" 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 "**Are you applying as an individual or on behalf of an organisation?***" 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 "**Select the organisation on behalf of which you are applying**", "**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 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**"; If there is more than one location visible, please select the location listed in your Wholesale Distribution Licence and request de-activation of other locations by logging to your OMS account.
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 at least two managers who will have rights to manage 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 "New Draft submission" (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 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. Click on "**Parallel Distribution Notice Status**" to select the new status of the notices to make them dormant, active or to withdraw the notices.
16. Click "**Yes**" to confirm you agree to the obligations detailed (for "Active" and "Withdrawn" only).
17. Back in the main "**Submission Form**" screen, click on "**Documents from industry**"; if no documents are required for this type of submission, so tick '**No**' and click '**Save and Return**';

18. 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;
19. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;
20. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list that appears;
21. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
22. Repeat steps "20" to "21" until you are ready for final submission;
23. Click on the "**Submit Application**" button;
24. Confirm the declaration(s) and then click "**Declaration and Submission**";
25. 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;
26. If you are sure you want to submit the application, click "**Submit**".

6. How to create Change of name and/or address

N.B. Before changing company name and/ or address in IRIS, please request a change in OMS (refer to the OMS guide in [IRIS guide to registration](#))

1. From the IRIS portal home page, click on "**Draft submissions**";
2. Click "**Create new submission**" [a screen with the heading "New Draft Submission" opens. The first stage "**1. Choose Applicant Type**" is highlighted in blue];
3. From the drop-down arrow on the box below "**Are you applying as an individual or on behalf of an organisation?***" 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 "**Select the organisation on behalf of which you are applying**" "**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**"; If there is more than one location visible, please select the current location listed in your Wholesale Distribution Licence.
8. Use the search symbol to look up the submission types available, click on "**Change of Name and Address**" and "**Select**";

9. Use the search symbol to look up the affiliated managers available for you to select, pick at least two managers who will have rights to manage this submission and click "Continue to Submission form";
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 "Submission Form" 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 "Submission form" screen a procedure type of your draft submission and a reference number (e.g. EMA/PD/0000001234) are displayed. (N.B. It is a good idea to take note of the reference number created). There is also now a list of five steps relating to the procedure, displayed on the left-hand side of your screen, each of which will be followed by a 'green tick' once completed;
14. Click on "**Update name and/or address**" to bring up a screen on which you will see "Current name and/or address" and "New name and/or address" fields;
15. Click on "**Select**" and select the new name and/or address for your company.
16. A field "New name and/or address" updates once the information has successfully been entered. Click "**Save and return**".
17. Click "**Submission details**" – this will open a window to add all the information relevant to the change. Click "**Save and return**".
18. Click "**Documents from industry**" and via "**Add files**" button attach the relevant documents (e.g. new WDA), confirm the upload, click "**Save and return**".
19. "**Documents from EMA**" will contain documents from EMA (if applicable).
20. Click "**Declaration**", confirm the statement, click "**Save and return**".
21. Click "**Submit Application**".
22. Confirm the declaration(s) and then click "**Declaration and Submission**";
23. 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;
24. If you are sure you want to submit the application, click "**Submit**".

7. How to create Change of Manufacturer (=Repackager for Parallel distribution purposes)

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

2. Click "**Create new submission**" [a screen with the heading "Draft 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 "**Are you applying as an individual or on behalf of an organisation?***" 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 "**Select the organisation on behalf of which you are applying**", "**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 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**"; If there is more than one location visible, please select the current location listed in your Wholesale Distribution Licence.
8. Use the search symbol to look up the submission types available, click on "**Change of Manufacturer**" and "**Select**";
9. Use the search symbol to look up the affiliated managers available for you to select, pick at least two managers who will have rights to manage 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 "New Draft 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 "Submission form" screen a procedure type of your draft submission and a reference number (e.g. EMA/PD/0000001234) are displayed. (N.B. It is a good idea to take note of the reference number created). There is also now a list of seven steps relating to the procedure, 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 to provide a purchase order number and your customer account number; click "**Save and Return**";
15. Click on "**Select Parallel Distribution Notices**" and "**Select All Notices**"; click "**Save and Return**";
16. Add and remove repackages as necessary in the relevant fields; click "**Save and return**";
17. Click "**Documents from industry**" and via "**Add files**" button attach the relevant documents (e.g. new licence), confirm the upload, click "**Save and return**".
18. "**Documents from EMA**" will contain documents from EMA (if applicable)
19. Click "**Declaration**", confirm the statement, click "**Save and return**".

20. Click "**Submit Application**".
21. Confirm the declaration(s) and then click "**Declaration and Submission**";
22. 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;
23. If you are sure you want to submit the application, click "**Submit**".

8. How to add contributors/managers to a draft PD notification

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

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

1. Click on "**Ongoing submissions**" or "**Draft submissions**";
2. Find the application you want to amend;
3. On the right-hand side, click on the drop-down arrow and select "**View/Manage Contributors (or Managers)**";
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/manager;
6. Click "**Add**", then "**Done**";
7. To add more contributors to the same application, repeat steps 4. to 6. above.

9. How to add submission contact person to a PD notification

You can add an additional contact person to your submission which will transfer the management rights to a new person provided he/she is also a second/third manager for that submission.

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

1. Click on "**Ongoing submissions**" or "**Draft submissions**";
2. Find the application you want to amend;
3. On the right-hand side, click on the drop-down arrow and select "**Manage submission contact**";
4. "**Portal – Draft – Manage Submission Contact**" window will open.
5. Click "**Change submission contact**" and choose the new contact from the list, click "**Select**", then click "**Save and return**".

10. How to delete a draft application

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

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

11. How to display and sort submissions

1. From the IRIS portal home page, click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";
2. 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;
3. 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.

12. How to search for submissions

1. From the IRIS portal home page, click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";
2. 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;
3. 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");

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

13. 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 depending on the regulatory check outcome amend the submission and/or upload the updated documents:

1. From the IRIS portal home page, click on "**Ongoing submissions**";
 2. Locate the submission mentioned in the e-mail by using the sort or search features described earlier in this guide, or by just scrolling down the list until you find it;
 3. At the end of the row in the list where your submission appears, click on the drop-down arrow and select "**View/edit submission**";
 4. 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.);
 5. 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;
 6. If you need to upload documents, click on "**Documents**" and then on "**Add**" to provide documents requested by the Agency;
 7. Click on "**Upload**" (button with an arrow going up) - the documents are now uploaded in the document folder;
 8. Click "**Submit application**", confirm the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;
 9. Click on the "**Declaration and submission**" button;
 10. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click "**Review application**" and this will return you to the draft submission;
 11. If you are sure you want to submit the application, click "**Submit**";
 12. Your updated application has now been submitted.
13. If you need to reply to the regulatory check email, hit "Reply" in the Outlook, but do not change the subject line of the email.