



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2022
EMA/805961/2018
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](#).

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



© European Medicines Agency, 2022. Reproduction is authorised provided the source is acknowledged.

Contents

Purpose and context	1
1. How to create a submission for parallel distribution	3
2. How to create an initial notification for parallel distribution <i>new</i>	4
3. How to create a safety update <i>new</i>.....	6
4. How to create an Annual Update for parallel distribution <i>new</i>	7
5. Notifying scopes of changes in an annual update.....	8
6. How to create an update of parallel distribution notice status	10
7. How to create Change of name and/or address	11
8. How to create Change of Manufacturer (=Repackeger for parallel distribution purposes)	12
9. How to create Reassignment of notices for parallel distribution	13
10. How to add contributors/managers to a draft PD notification	14
11. How to add submission contact person to a PD notification	14
12. How to display and sort submissions	15
13. How to search for submissions	15
14. How to respond to a notification email from EMA requesting VSI	15
15. How to delete a draft case or withdraw a submitted case – all submission types	16

1. How to create a submission for parallel distribution

N.B. The steps below are initial steps for creating **any** Parallel Distribution submission.

1. From the IRIS portal home page, click on "**Submissions**", then "**My 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 3 mandatory fields appear labelled "Select the organisation on behalf of which you are applying", "Location", "Submission Type";
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). Pick the right organisation (there may only be one) and click "**Select**";
6. 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, **select name and legally registered address of WDA holder location listed in your Wholesale Distribution Licence** (N.B. not other "site" addresses) and request de-activation of other locations by logging to your OMS account.
7. Use the search symbol to look up the submission types available, click on the required submission type (e.g. "Initial Notification for Parallel Distribution" or "Safety Update", etc.), "**Select**"; then click "**Create and Next**";

N.B. System will auto-assign the user, creating any submission request, as Manager.

8. On page "Add Managers & Contributors" choose additional managers or contributors via the "**Add**" buttons and then magnifying glass search symbol will bring up a list of people to select as managers and/ or 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);
9. If there are names on the list, select one or more managers and/or contributors and their names will appear on the main "New Draft Submission" screen (N.B. It is advisable to choose one additional manager/ contributor to the case so more than one person has access to the said case. You can also add and remove contributors later on);
10. Click "**Continue to submission form**".

After steps 1-10, follow the guide section for your chosen procedure, below.

2. 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. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. 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;
3. 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 your invoice. Your SAP customer number will be provided by the system in the field "Customer account number". If the number is correct, please confirm it with a "Yes"; if the number is incorrect or missing, click "No" and enter your correct customer account number in the field "Please provide customer account number", then click on **"Save and return"**;
4. 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"**;
5. Indicate whether the pack size has been changed (i.e. sourced pack size is different from the distributed pack size) and if yes, search for the product presentation/-s being sourced by clicking on **"Add"**. Then click **"Save and Return"** to return to the Submission Form page;
6. Click on **"Member States of Origin and Destination"** to indicate the MSO(s) and MSD(s) by clicking **"Add"** in each category;
7. Select **"Yes"** or **"No"** as applicable for the Specific Mechanism. If "Yes", the **"Date of prior notification"** field 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."** (N.B. a dash or "N/A" is not a valid justification). Then click **"Save and Return"**;
8. 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"**; **N.B. At least one of the repackagers must hold a Manufacturing Importation Authorisation (MIA) licence with secondary repackaging authorised and the address of that repackager must correspond to the manufacturing site address of that MIA.**
9. Back in the main "Submission Form" page, click on **"Nature of Repackaging"**; in the next screen that appears, the first question "Is modification to the packaging proposed?" will default to "Yes", as this will always apply to an initial notification for parallel distribution (N.B. do not change it to "No");
10. Indicate the repackaging nature chosen, but ticking "relabelling", "reboxing", or "relabelling and reboxing". Details can be provided in the field below; The "Date of the latest product information update" (annex used) should be indicated. Then click **"Save and Return"**;

11. Back in the main "Submission Form" page, click on "**Documents from Applicant**"; click on "**Add files**" to upload the documents; the pop-up window¹ that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA.

In the section below indicate the package leaflet, mock-up of the outer packaging/labelling and mock-up of the inner labelling among other submitted documents, and the language(s) of these documents by either clicking the document that you uploaded under "Document name" column or the drop-down button on the right (the button will give an "edit" option).

A "View details" window will open: select the document type "package leaflet" (or "mock-up of outer packaging", or "mock-up of inner labelling") from the drop-down list as applicable, and indicate the language of that document. With multiple languages, indicate 2 or 3, accordingly. Other submitted documents don't require identification.

12. Confirm with a "Yes" that the listed documents have been provided and click "**Save and Return**";
13. You have now successfully created a draft submission which will now appear in your "**My Draft Submissions**"; you can add more information when you are ready to do so;
14. When you want to add more information, click on "**Submissions**"; then "**My Draft submissions**" and find the draft submission you want to edit;
15. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list;
16. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
17. Repeat steps 14-16 until you are ready for final submission;
18. When you are ready to submit your final application, click on "**Declaration**" and confirm all the statements; click "**Save and Return**";
19. 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;
20. 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;
21. 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 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 finalised by the Agency can be found in "My Draft Submissions" and "Completed Submissions" respectively.

1 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.

3. How to create a safety update

1. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. 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;
3. 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;
4. Back in the main "**Submission Form**" screen, click on "**Documents from Applicant**";
5. Click on the blue "**Add files**" to upload documents; add the relevant document(s) into the folder; The pop-up window² that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA.

In the section below indicate the package leaflet, mock-up of the outer packaging/labelling and mock-up of the inner labelling among other submitted documents, and the language(s) of these documents by either clicking the document that you uploaded under "Document name" column or the drop-down button on the right (the button will give an "edit" option).

A "View details" window will open: select the document type "package leaflet" (or "mock-up of outer packaging", or "mock-up of inner labelling") from the drop-down list as applicable, and indicate the language of that document. With multiple languages, indicate 2 or 3, accordingly. Other submitted documents don't require identification.

6. Confirm that the listed documents and a Text Comparison Report, if applicable, have been provided; provide the product information used date (annex date), then click "**Save and return**".
7. 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;
8. When you want to add more information, click on "**Submissions**"; then "**My Draft submissions**" find the draft submission you want to edit;
9. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list that appears;
10. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
11. Repeat steps 9-11 until you are ready for final submission;

² 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.

12. When you are ready to submit your final application, click on "**Declaration**"; click on the tick boxes of the declaration statements to confirm all statements and click "**Save and Return**";
13. Click on the "**Submit Application**";
14. Confirm the declaration and then click "**Declaration and Submission**";
15. 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;
16. If you are sure you want to submit the application, click "**Submit**".

4. How to create an annual update for parallel distribution

1. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. A reference number (e.g. EMA/PD/000000**1111**) 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 "**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 your invoice. Your SAP customer number will be provided by the system in the field "Customer account number". If the number is correct, please confirm it with a "Yes"; if the number is incorrect or missing, click "No" and enter your correct customer account number in the field "Please provide customer account number", then click on "**Save and return**";
4. 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; please select exact pharmaceutical form (see product information (annex)).
5. Click "**Yes**" or "**No**" in the field "Are you informing the EMA of any changes to the selected notices?", then click "**Return**";
6. In the "**Documents from Applicant**" folder add documents via "**Add files**" button. The pop-up window³ that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA

In the section below indicate the package leaflet, mock-up of the outer packaging/labelling and mock-up of the inner labelling among other submitted documents, and the language(s) of these documents by either clicking the document that you uploaded under "Document name" column or the drop-down button on the right (the button will give an "edit" option).

A "View details" window will open: select the document type "package leaflet" (or "mock-up of outer packaging", or "mock-up of inner labelling") from the drop-down list as applicable, and indicate the

³ 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.

language of that document. With multiple languages, indicate 2 or 3, accordingly. Other submitted documents don't require identification.

7. Confirm that the listed documents and a Text Comparison Report, if applicable, have been provided; provide the product information used date (annex date), then **click "Save and return"**.
8. The **"Documents from EMA"** folder is empty at this stage but will contain documents provided by EMA during the process;
9. Click on **"Declaration"** and tick all boxes to confirm statements accordingly, then **"Save and return"**;
10. If you have **no changes** to report or the only scope of change is update of the product information in line with a new annex, please **"Submit Submission"** at this stage; N.B. **Do not create a scope of change submission**;
11. 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);

5. Notifying scopes of changes in an annual update

1. Back in the Draft Submissions, Click on **"Create new submission"** and then go through 1-10 in section **1. How to create a submission for parallel distribution**; choosing **"Annual Update – Scopes of Change"** as the submission type;
2. Click **"Continue to submission form"** and a reference number (e.g. EMA/PD/000000**2222**) 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 via **"Add"** button search/select the Regulatory Entitlements for which you wish to notify the changes, **"Save and Return"**, the Regulatory entitlements should be **grouped by scopes of change** (i.e. "Add or Remove Details of Repackagers/ Member States of Origin, etc.");
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 scopes of changes or to notify about a further set of scopes of changes to other Regulatory Entitlements within **this** 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 change" and choose **"Clone submission"** in order to create another scope entry ("Annual Update – Scopes of change") for the same annual update with the exact company information (this allows you to skip the first couple of steps within the submission forms);
8. The cloned draft (of e.g. EMA/PD/000000**2222**) will now appear in your draft list, with its own procedure number, e.g. EMA/PD/000000**3333** (it is worth noting it down);
9. Click on the drop-down arrow to the right of this cloned draft and select **"Edit Draft"** in order to input the relevant information as per steps 3 – 6 above;

10. 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 (EMA/PD/0000001111), click on the drop down arrow to the right, and go to "**Edit draft**";
11. In the "Submission Form" screen 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" entries related to this annual update;
12. To proceed with the submission, click on "**Submit application**" and tick relevant statement(s), then click "**Declaration and submission**", then "**Submit**";

N.B. For annual updates withdrawals, see section 15.

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

1. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution;**
2. 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;
3. 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;
4. Click on "**Parallel Distribution Notice Status**" to select the new status of the notices to make them dormant, active or to withdraw the notices. Click "**Yes**" to confirm you agree to the obligations detailed (for "Active" and "Withdrawn" only); click '**Save and Return**';
5. Back in the main "**Submission Form**" screen, click on "**Documents from Applicant**"; if no documents are required for this type of submission, tick '**No**' and click '**Save and Return**';
6. 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;
7. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;
8. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list that appears; make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
9. Repeat steps "20" to "21" until you are ready for final submission;
10. Click on the "**Submit Application**" button;
11. Confirm the declaration(s) and then click "**Declaration and Submission**";
12. 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;
13. If you are sure you want to submit the application, click "**Submit**".

7. 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. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. 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;
3. "Regulatory entitlement overview" is a list of your regulatory entitlements;
1. Click on "**Update name and/or address**" to bring up a screen in which you will see "Current name and/or address" and "New name and/or address" fields; click on "**Select**" and select the new name and/or address for your company;
2. A field "New name and/or address" updates once the information has successfully been entered. Click "**Save and return**";
3. Click "**Submission details**" – this will open a window to add all the information relevant to the change. Click "**Save and return**";
4. Click "**Documents from Applicant**" and via "**Add files**" button attach the relevant documents (e.g. new WDA), confirm the upload, click "**Save and return**";
5. "**Documents from EMA**" will contain documents from EMA (if applicable);
6. Click "**Declaration**", confirm the statement, click "**Save and return**";
7. Click "**Submit Application**";
8. Confirm the declaration(s) and then click "**Declaration and Submission**";
9. 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;
10. If you are sure you want to submit the application, click "**Submit**".

8. How to create change of manufacturer (=repackager for parallel distribution purposes)

N.B. Before reporting change of manufacturer in IRIS, please ensure the repackager is registered in OMS (refer to the OMS guide in [IRIS guide to registration](#))

1. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. 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;
3. Click on "**Parallel Distributor information**" to bring up a screen to provide a purchase order number and your customer account number (your SAP customer number will be provided by the system in the field "Customer account number". If the number is correct, please confirm it with a "Yes"; if the number is incorrect or missing, click "No" and enter your correct customer account number in the field "Please provide customer account number"). Click on "**Save and return**";
4. Click "**Save and Return**";
5. Click on "**Select Parallel Distribution Notices**" and "**Select All Notices**"; click "**Save and Return**";
6. In "Add or Remove Repackagers" screen add and remove repackages as necessary in the relevant fields; click "**Save and return**";
7. Click "**Documents from Applicant**" and via "**Add files**" button attach the relevant documents (e.g. new licence), confirm the upload, click "**Save and return**";
8. "**Documents from EMA**" will contain documents from EMA (if applicable);
9. Click "**Declaration**", confirm the statement, click "**Save and return**";
10. Click "**Submit Application**".
11. Confirm the declaration(s) and then click "**Declaration and Submission**";
12. 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;
13. If you are sure you want to submit the application, click "**Submit**".

9. How to create reassignment of notices for parallel distribution

N.B. Before reassigning notices in IRIS, please ensure the other company is registered in OMS (refer to the OMS guide in [IRIS guide to registration](#))

1. Follow the steps 1-10 in section **1. How to create a submission for parallel distribution**;
2. 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 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;
3. Click on "**Parallel Distributor Information**" to bring up a screen for your **invoice and account numbers**; fill those in (your SAP customer number will be provided by the system in the field "Customer account number". If the number is correct, please confirm it with a "Yes"; if the number is incorrect or missing, click "No" and enter your correct customer account number in the field "Please provide customer account number"), click "**Save and return**";
4. Click on "**Reassignment Details**" and select the new company; click "**Save and return**";
5. Click "**Documents from Applicant**" and via "**Add files**" button attach the relevant documents, confirm the upload, click "**Save and return**";
6. "**Documents from EMA**" will contain documents from EMA (if applicable);
7. Click "**Declaration**", confirm the statements, click "**Save and return**";
8. Click "**Submit Application**", confirm the declaration(s) and then click "**Submit Application**" – a "**Confirm Submission**" box will pop up;
9. 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;
10. If you are sure you want to submit the application, click "**Submit**".

10. How to add contributors/managers to a 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 "**My 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.

11. 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 "**My 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**".

12. 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: **"My 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.

13. 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: **"My 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.

14. 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 validation or regulatory check outcome 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. Click on "**Documents from Applicant**" and then on "**Add**" to provide documents requested by the Agency;
5. Click on "**Upload**" (button with an arrow going up) - the documents are now uploaded in the document folder;
6. 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;
7. Click on the "**Declaration and submission**" button;
8. 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;
9. If you are sure you want to submit the application, click "**Submit**";
10. Your updated application has now been submitted.
11. 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.

15. How to delete a draft case or withdraw a submitted case

N.B.:

- Draft submissions can be deleted or edited anytime. Submitted submissions have a 24-hour window to be withdrawn free of charge: if withdrawal is requested within 24 hours of submission, it is free of charge. If withdrawn later, the fees will apply.

- You can delete a draft application that you yourself have created as an "Industry Manager" role.

1. From the IRIS portal home page, click on "**My Draft submissions**";
2. Locate the **draft submission that you want to delete**; click on the drop-down arrow to the right, click "**Delete draft**"; a confirmation message will open up in a new window;
3. Confirm the request to delete.

«»

1. From the IRIS portal home page, click on "**Ongoing submissions**";
2. Locate the **submitted submission that you want to withdraw**; click on the drop-down arrow to the right, and click "**View/Edit Submission**";
 - i. If you need to withdraw the annual update scope of change submission, note that it alone cannot be withdrawn, but the related annual update needs to be withdrawn, which will in turn withdraw the related scope of change
3. Once within the case, click "**Withdraw Submission**" button at the bottom of the page; a confirmation message will open up in a new window;

4. Confirm the request to withdraw.
5. **"Withdrawal requested"** will display in "Submission status" and "Case status" columns.
6. Once processed at EMA, the withdrawn case will appear in "Completed Submissions" with "Case Status" indicating **"Completed-Withdrawn"**.

N.B. You cannot withdraw a case from "Completed Submissions" section. Please see Section "5. How to create an update of parallel distribution notice status".