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IRIS guide for applicants

How to create, submit and manage IRIS applications, for industry and individual applicants

Version 3.10

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Revision history

Date	Description
27/06/22	Added Section 9. Registration of an MAH i-SPOC on supply and availability
05/09/22	Section 7. Inspections updated
10/10/22	Section 4. Scientific Advice updated
03/05/23	Section 8. Veterinary Signal Management updated
10/07/23	Added Section 10. PRIME Eligibility
25/07/23	Merged the previously separate “IRIS guide to parallel distribution applicants” into Section 11 of this document, and added several minor updates
03/10/23	Section 10. PRIME Eligibility updated
21/11/23	Merge of IRIS guide to applicants and IRIS guide to parallel distribution applicants
18/01/24	Added instructions to manage regulatory procedures in IRIS in existing section and added a new section dedicated to Product Lifecycle Management procedures
04/06/24	Added Section 13. Paediatric medicines development Update of section 6.3 Marketing Status Notification (Bulk Upload) - Reason for Cessation Terms (highlighted in yellow)
06/08/24	Added Section 13.6.6. Changing contact person Updated section 13.3 Create an application for modification of Paediatric Investigation Plan (modification of an agreed PIP)
13/09/24	Added section 13.1.1. Submitting the response to PDCO request for modifications (RSI) Added section 2.13.3. My contact information management
10/12/24	Minor updates implemented in sections 2 and 12
20/12/24	Major updates to sections 4, 11, 13, minor updates to sections 2 and 7
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12/03/2025	Major updates to sections 1.1, 2.1, 2.4, 12, 12.1, 12.9, 14, minor updates to sections 2.11, 12.7. Added Annexes section, including table with procedure number format in IRIS Updated section 6.1. Revision of IRIS marketing status term details to provide clarity and addition of shortage reporting requirements via ESMP

Date	Description
11/07/2025	Added section 2.10 Documents from EMA and Industry in IRIS and section 2.11 Receipt date of documents from EMA Updated section 12.10 Re-examination
25/07/2025	Updated sections: 13.1. Create an application for initial paediatric investigation plan (PIP) 13.1.1 Submitting the response to Paediatric Committee request for supplementary information and modification of proposed PIP (RSI) 14.1 Addition of paediatric procedure format in annexes table
13/10/2025	Updated sections: 11.7 Create change of name and/or address on notices for parallel distribution

Acronym key and glossary terms

Abbreviation	Explanation
CAP	Centrally Authorised Product
CHMP	Committee for Human Medicinal Products
COMP	Committee for Orphan Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
EC	European Commission
EMA	European Medicines Agency
ESMP	European Shortages Monitoring platform
ETF	Emergency Task Force
EU	European Union
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IAM	Identity & Access Management
ITF	Innovation Task Force
LoQ	List of Questions
MS	Member State
MSSG	Medicine Shortages Steering Group
OD	Orphan Designation
OMS	Organisation Management Service (part of SPOR)
PD	Parallel Distribution
PDCO	Paediatric Committee
PIP	Paediatric investigation plans
PLM	Product lifecycle management
PRIME	Priority medicines
RPI	Research Product Identifier
SA	Scientific Advice
SME	Subject Matter Expert
SPOR	Management Services for Substances, Products, Organisations and Referential Terms

1. Purpose and context

1.1. Purpose of this guide

This guide has been produced to show applicants how to use the IRIS platform to prepare, submit and manage an application and/or data for a **scientific procedure** (orphan designation application, scientific advice, ITF briefing meeting requests, PRIME, marketing status reports, inspections and veterinary signal management) and related activities, or applications for **Parallel Distribution** procedures. Please note that for Parallel Distribution submissions separate user access roles are needed (it is possible to combine the roles; see the IRIS guide to registration and RPIs for more details).

This guide also describes how to use the IRIS platform for **product lifecycle procedure management** (variations and Art. 61(3) notifications under Directive 2001/83/EC, variations requiring assessment under Regulation 2019/6, Marketing Authorisation transfer applications, Post-authorisation measures (PAM), Annual reassessment, Referrals, Post-authorisation safety study (PASS)/ Post-marketing surveillance studies (PMSS), Line extensions, Renewals for human and veterinary medicinal products, Periodic safety update reports (PSURs)) (further in the document PLM) after the submission has been created by EMA based on Applicant's electronic application form (eAF) and dossier submitted through the eSubmission Gateway or eSubmission Web Client.

1.2. Preliminary requirement

EMA Account and appropriate role: for any type of submission in IRIS, you need an EMA account and an appropriate role in IRIS, to login into IRIS. Registration needs to be done only once and will allow you to submit and manage any type of scientific applications now and in the future. For information on how to request an EMA account and an appropriate IRIS role (these are two separate actions), please consult the separate IRIS guide to registration and the quick interactive guide to IRIS registration process on the IRIS home page. This guide also contains information on how to request or transfer an **RPI (Research Product Identifier**, see below**)**.

1.3. Supported browsers

IRIS can be accessed on any modern Web Browser, including but not limited to Google Chrome (latest version), Edge (the new, Chromium-based Edge is recommended), Safari 12 and above, Firefox (latest version), Vivaldi, etc. An updated version of the browser is recommended.

2. Common operations for all submission types

2.1. Display and sort submissions

From the IRIS home page, after sign-in, click on any of the options: "**My Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**" present under "**Submissions**" Tab.

If you have an IRIS Industry Manager/IRIS Parallel distribution Manager role, you will see all the submissions that you have created, plus all the submissions in which you have been added as a manager.

If you have IRIS Industry Contributor role, you will see all the Submissions to which you have been added as a Contributor.

If you have IRIS Industry Coordinator, you will see any submission/application made on behalf of an organisation.

In all cases, you will see submissions only if you are affiliated to the correct organisation in IAM. For more information on IRIS Access roles and permissions see the "IRIS guide to registration and RPIs" for further details.

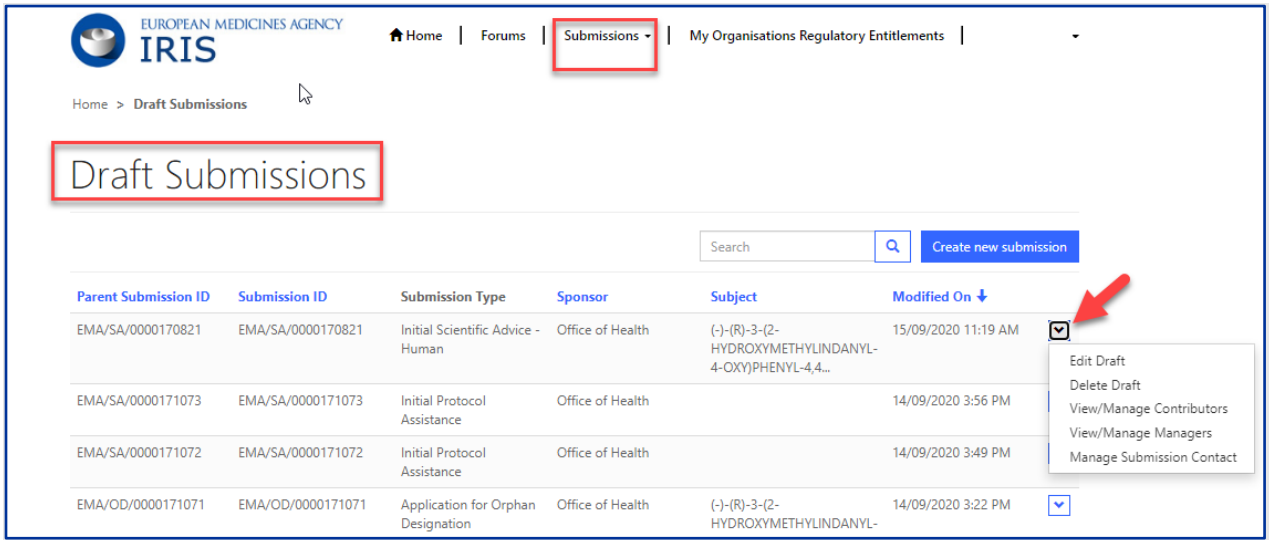
Click on any of the column headings that appear in blue font, and the rows listed in the table will be sorted in ascending order (click again for descending order).

2.2. Search for submissions

You can obtain a restricted subset of your submissions:

1. From the IRIS home page, select first "**My Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";
2. In the search bar, enter any string (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"); by including an asterisk (*) as first character, the search string will apply to text in any position;
3. Click on the magnifying glass search symbol or press "**Enter**" on your keyboard to launch the search;
4. A list of the relevant results that match the search criterion you typed in the search bar will be displayed. The list can be sorted as described in the previous section;
5. In "**My Draft submissions**" and **"Ongoing submissions**", a menu of different actions can be elicited by clicking on the arrow pointing down on the rightmost of the relevant submission. You can edit or delete the submission, manage the contributors and managers, and change the "**Submission contact**" (the person who will receive by default all the email communications for the procedure, also known as "Portal contact") (see Figure 1. Managing draft submissions).

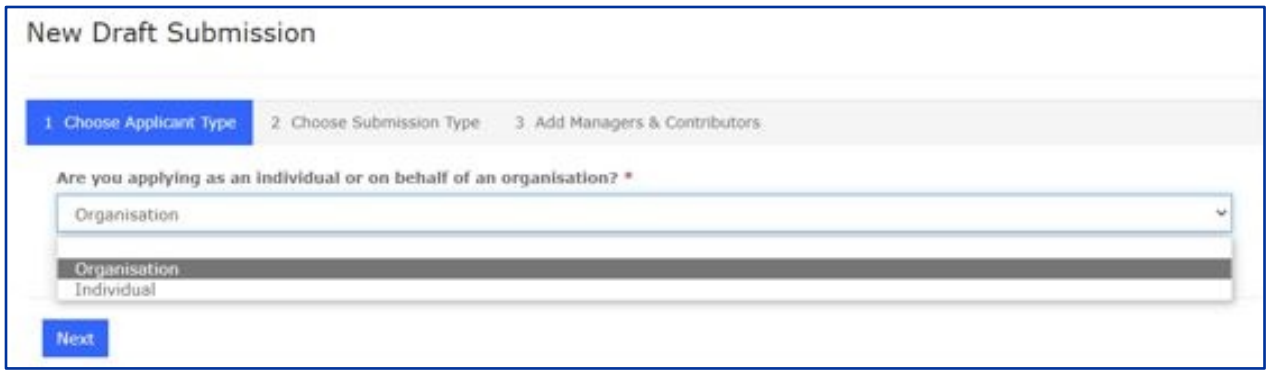
Figure 1. Managing draft submissions



2.3. Create a new submission (general procedure for all submission types, except PLM procedures)

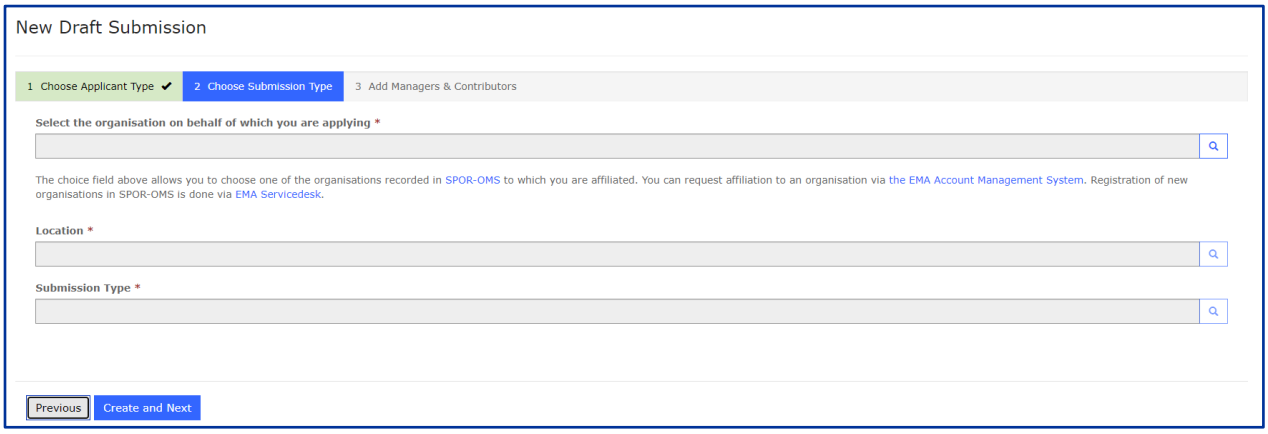
1. From the IRIS home page, click on "Submissions" tab then on
2. **"My Draft submissions"** Click on **"Create new submission"** [a screen with the heading "New Draft Submissions opens showing 3 stages.
3. The first stage **"1. Choose Applicant Type"** is highlighted in blue;
4. From the drop-down arrow on the box below "**Are you applying as an individual or on behalf of an organisation?**" select the appropriate answer and click "**Next**";

Figure 2. Creating a new submission



5. Only if you are applying on behalf of an organisation:
6. The second stage **"Choose Submission Type"** is now coloured blue and 3 mandatory fields (marked with a red asterisk "*") appear labelled **"Organisation" "Location"** and **"Submission Type"** (the first two only if you are applying on behalf of an organisation). Use the search symbol to look up the submission types available, click on the appropriate submission type and then on **"Select"**;

Figure 3. Creating a new submission



7. 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);

8. Pick the right organisation and (there may only be one) and click **“Select”**;

9. Use the search symbol to look up the locations available for you to select, pick the right one and click **“Select”**; please note that the Regulatory entitlement (Orphan Designation) will be granted to the address of this location and the relevant organisation;

NOTE: it is strongly recommended to use only one location (normally the legal seat of the organisation) for all IRIS submissions, RPIs and regulatory entitlements. This simplifies your management of submissions in IRIS.

Click on ‘Create and Next’

10. The third stage is **“3. Add Managers and Contributors”** where you are asked **to add at least one Manager** in the specific field (when applying on behalf of an organisation, the pop-up list will only include those people who have been granted an IRIS Industry Manager/IRIS Parallel Distribution Manager 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).

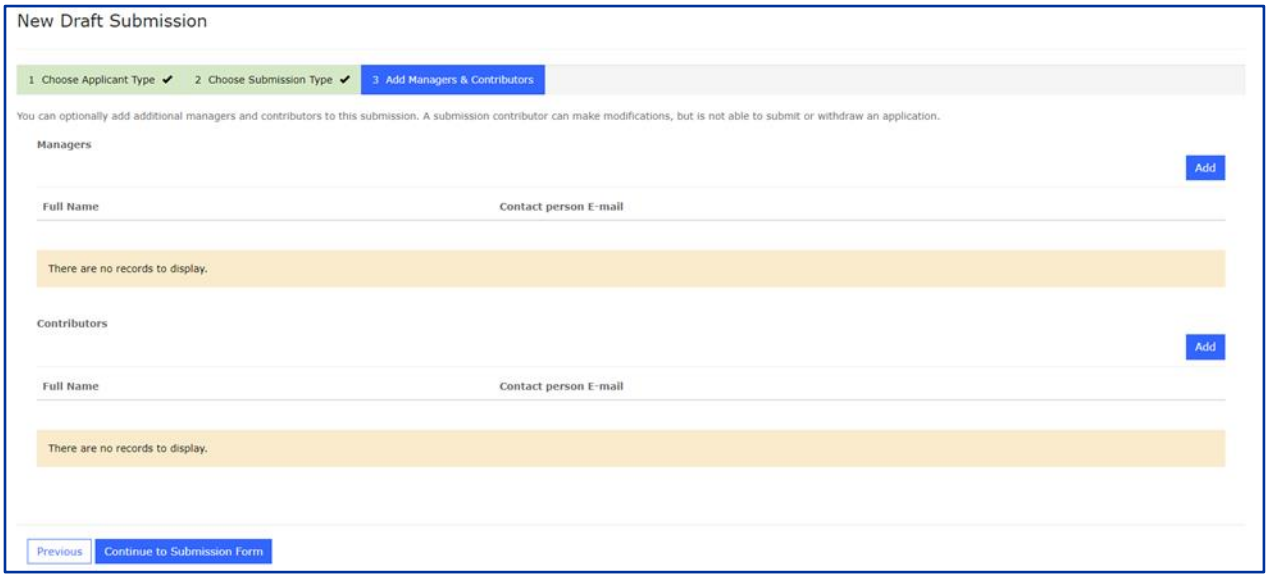
11. Use the search symbol to look up the names with Manager access, click on the name to be added and then on **“Select”**;

12.

Additional managers and contributors can be optionally added to the submission. A submission contributor can make modifications but is not able to submit or withdraw an application.

It is strongly recommended to have at least two Managers (preferably three) for each IRIS submission: this will allow the applicant continued access to the submission even if one of the managers leaves the company or is absent for prolonged periods;

Figure 4. Creating a new submission

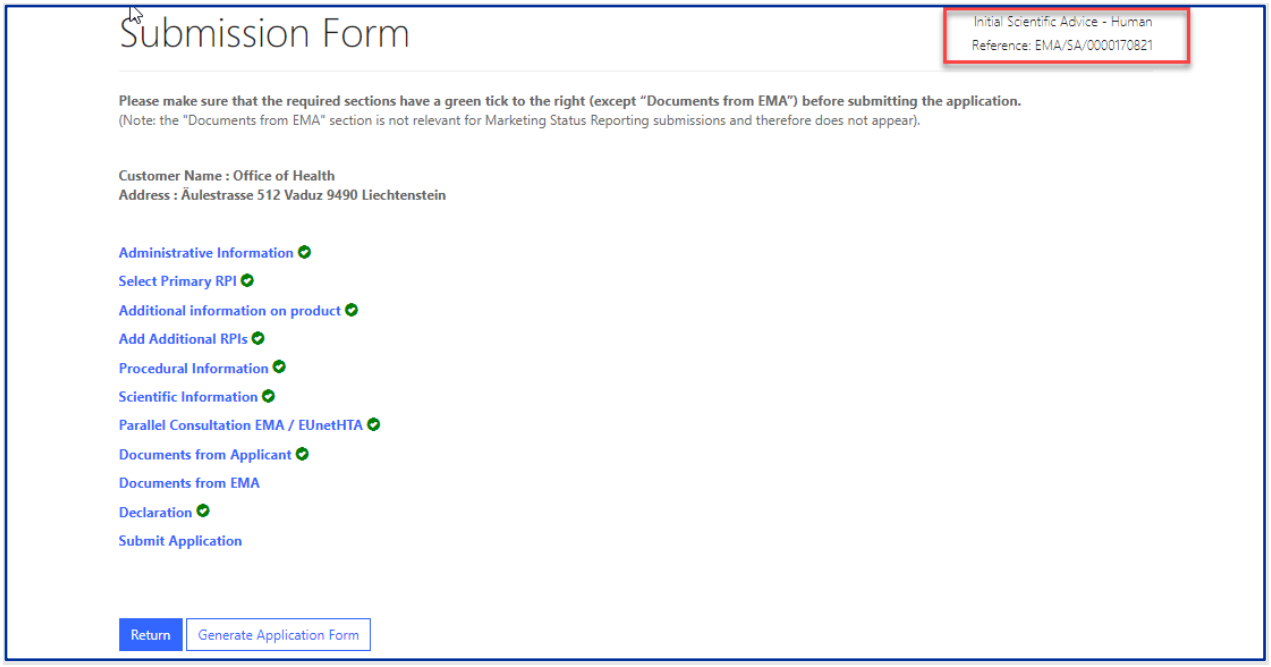


13. Click "**Continue to Submission Form**". A new screen appears with a reference number (e.g. EMA/XX/0000001234) for your draft submission displayed on the upper right-hand side of the "Portal – New Submission" screen (N.B. It is a good idea to take note of the reference number created).

14. You will see a list of various tabs (steps), possibly including "**Select RPI**" (for some scientific submissions) and usually ending with "**Declaration**"). **The list of tabs depends on the type of submission.**

15. A submission reference number is displayed on top right of your screen (see Figure 5. Example of new submission).

Figure 5. Example of new submission



16. If a "select primary RPI" tab is present (scientific applications), click on **"Select RPI"** to bring up "Research Product Identifier (RPI)" screen:

    - Click the **magnifying glass** search symbol to bring up a list of RPI names;
    - In the pop-up window, pick an RPI name from the list and click "**Select**";
    - Back in the "Research Product Identifier (RPI)" screen, click "**Save and Return**" and you are returned to the "Submission Form" screen;

RPI information for Scientific Applications
(not applicable to Parallel Distribution or Marketing status submissions)

If you do not see the RPI for your product in the list, please see the detailed information on RPIs in the section 8.1 of the IRIS guide to registration and RPIs in the IRIS guidance webpage.

17. Once mandatory sections (tabs, including RPI where applicable) are completed, all the sections will turn from grey to blue and will be active (see Figure 5. Example of new submission). Fill in each section. Please note that fields with a red asterisk are mandatory. You need to complete each section before you can save it, but it is not mandatory to fill in all the section in one session.

18. Back in the main "Submission Form" Screen, click on "Documents from Applicant";

19. In the next screen that appears, for some submissions you can directly upload documents to your submission. While there is no maximum number of files or global size, there is a size limit of 50 Mb per file. Please upload individual files for each document, rather than a single Zip file (or similar) for the set of all documents; it is possible to upload multiple files in a single operation. If appropriate, you can merge several PDF files into a single one, using specific

software, before uploading. A Zip file is recommended only as the container for the literature references; all other documents should be submitted individually.

20. Click **“Save and Return”** when you have finished uploading documents;
21. At any stage during the procedure above, clicking “**Return**” on the Submission form page saves the draft submission (which will now appear in your “**Draft Submissions**” list). You can open it again at a later time to edit/add more information;
22. Click on **“Generate Application form”** present at bottom of screen next to **“Return”** button to create a word file for the summary of application filled at that point of time by the applicant. Word file will be shown under **“Documents from Applicant”;**

When you are ready to submit your final application, click on “**Declaration and re(submission)**”:

23. **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;
24. Click on the “Declaration and submission” button;
25. 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;
26. If you are sure you want to submit the application, click” Submit”.

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

You are then returned to the portal **“Ongoing Submissions”** tab. You can now look up the submission you have just submitted using the **“Ongoing Submission”.** The latest submission will appear on top once validation is completed in background, as submissions are sorted by date and time of last update.

2.4. Communication only to the submission contact (portal contact) for a submission

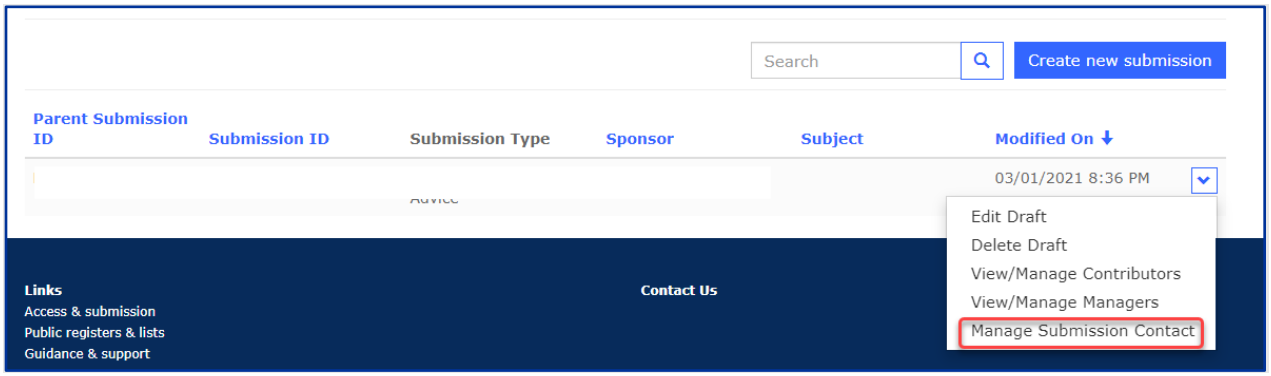
The communication model for IRIS is that while there can be any number of Industry/Parallel distribution managers and Industry contributors/Parallel distribution associated to a single submission, only one of them is the "**submission contact**", also called the "**portal contact**" i.e. the primary contact person to whom all communication is sent (by default) for a given submission. The default "**submission contact**" is the Industry/Parallel distribution manager who submits the application. The default “**Submission Contact**” for PLM procedures led by EMA, is described in Chapter 12 Product Lifecycle Management (PLM) procedures.

The "**Submission Contact**" role can be reassigned at any moment for draft and ongoing submissions, and repeatedly, by any of the IRIS Industry/Parallel distribution Managers associated to that submission. However, EMA will by default send all the **communication** only to the single **"Submission Contact",** assigned in that moment. This is for efficiency and security reasons.

The applicants are advised to consider setting up appropriate auto-forwarding rules in the email system of the "Submission Contact".

The applicants can nominate additional IRIS Industry/Parallel distribution Managers and reassign the "Submission Contact" role as required, for example before a period of leave of the current "Submission Contact". This can be done in IRIS, by clicking on the arrow pointing down on the rightmost of the submission row in IRIS and selecting "Manage submission contact", as shown in Figure 6. Changing Submission (Portal) Contact and described in detail below the figure.

Figure 6. Changing Submission (Portal) Contact



From the IRIS home page, carry out the following steps (see also Figure 1. Managing draft submissions):

1. Click on “My Draft submissions”/“Ongoing submission” sub-tab present under “Submission” tab;
2. Scroll down and find the application you want from the list of your drafts/ongoing;
3. Click on the drop-down arrow on the right-hand side of the submission row and select “Manage Submission Contact” (Figure 6. Changing Submission (Portal) Contact);
4. Click “**Change submission contact**”, then in the pop-up window, select the name of the person you want to add as portal contact and click on “Select” (the list shows all managers associated with that submission); Note, that first the new “Submission contact” needs to be added as manager for the case (Chapter 2.5 Add managers to a draft/ongoing submission);
5. New portal contact will be shown in “Portal contact” field;
6. Click on “Save and Return”.

IRIS is being built to allow applicants to self-manage their "Submission contact" role for each submission. In future, EMA plans to extend this concept to self-management of the contact person and contact data for Products. Changes will be made by sponsor/marketing authorisation holders directly in the IRIS Industry portal.

2.5. Add managers to a draft/ongoing submission

You can insert additional managers to a submission also after the creation of submission, but only if the submission is in draft or ongoing status. This is not possible if the procedure has been completed.

You can add additional managers for the draft/ongoing applications for which you have a **"IRIS Industry Manager"** role (not if you are a Contributor). In addition, the Managers can edit, submit or withdraw the application.

From the IRIS home page, carry out the following steps (see also: Figure 1. Managing draft submissions):

1. Click on "My Draft submissions"/"Ongoing submissions" sub-tab present under "Submission" tab;
2. Scroll down and find the application you want from the list;
3. Click on the drop-down arrow on the right-hand side of the submission row and select "View/Manage Managers" as shown in Figure 6. Changing Submission (Portal) Contact;
4. Click "**Add**", then in the pop-up window, click the **magnifying glass search symbol** to bring up a list and find the name of the person you want to add as a manager;
5. Click "**Add**" again.

To add more managers to the same application, repeat the steps above.

2.6. Add contributors to a draft/ongoing submission

You can only do this for the draft and ongoing applications for which you have a **"Manager"** role (not if you have a Contributor or a Coordinator role).

From the IRIS home page, carry out the following steps (see also Figure 1. Managing draft submissions):

1. Click on "My Draft submissions"/"Ongoing submission" sub-tab present under "Submission" tab;
2. Scroll down and find the application you want from the list;
3. Click on the drop-down arrow on the right-hand side of the submission row and select "**View/Manage Contributors**";
4. Click "**Add**", then in the pop-up window, click the **magnifying glass search symbol** to bring up a list and find the name of the person you want to add as a contributor;
5. Click "**Add**" and "**Done**".

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

2.7. Delete a draft submission

You can only delete the draft applications for which you have a "Manager" role (not if you have a Contributor or a Coordinator role). Please note you cannot delete a "Completed submission", meanwhile, an "ongoing submission" can be withdrawn, using a similar procedure as described in section 2.8.

1. Click on “**My Draft submissions”** sub-tab present under **“Submission”** tab;
2. Find the application you want from the list of your drafts;
3. Click on the drop-down arrow on the right-hand side of the submission row and select “**Delete Draft**” and a confirmation message will open in a new window (see Figure 1. Managing draft submissionsFigure 1. Managing draft submissions);
4. Click on the "**Delete**" button to confirm that you want to delete your draft.

Note: you cannot undo the action once performed. After the draft submission is deleted from IRIS, the deletion is permanent, and the submission cannot be restored.

2.8. Automatic deletion of draft submissions

IRIS will scan all the submissions to identify those that have been inactive, meaning, there has not been any change in data of the submission for more than 7 months, and send an email to the “Submission contact” (a.k.a. “Portal contact”) to inform of the upcoming deletion of the submission unless a change is made to the submission in the following 2 weeks. If no change is made to the submission during that time, it will be deleted and definitively removed from the IRIS system, including any documents uploaded to IRIS. A final email will be sent to the submission contact, to notify the permanent removal of the submission from the system.

2.9. Documents from EMA and Industry in IRIS

To manage documents in IRIS, the Industry users have access to two below mentioned folders:

1. **Documents from Applicant**. In this folder Industry users upload the documents to be shared with EMA;
2. **Document from EMA**. In this folder Industry users access documents shared with them by EMA;

The folders can be accessed via Ongoing Submissions and Completed submission view.

For Ongoing submissions:

1. Click on "Ongoing Submissions" sub-tab present under “Submission” tab;
2. Find the submission you want to access documents from the list of your “Ongoing Submissions”;
3. Click on the drop-down arrow on the right-hand side of the submission row and select “View/Edit submission” and both folders Documents from Applicant and Document from EMA will be available under the submission form;

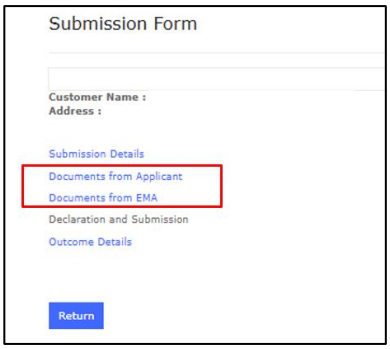
For Completed submissions:

4. Click on "Completed" sub-tab present under “Submission” tab;

5. Find the submission you want to access documents from the list of your “Completed Submissions”;

6. Click on the arrow on the right-hand side of the submission row and select “View” and both folders Documents from Applicant and Document from EMA will be available under the submission form;

Figure 8. Documents in IRIS



2.10. Receipt date of documents from EMA

A document shall be deemed received on the date the notification email is sent by the EMA to the applicant/ MAH indicating that a new document is available in the IRIS portal.

The foregoing is without prejudice to the provisions set out in Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits.

2.11. Respond to a notification email from EMA requesting changes

On receipt of a notification email from EMA stating for example that “Validation Supplementary Information (VSI)” is required for one of your Ongoing Submissions, or if any changes/updates are needed to the submission data in IRIS, log into the IRIS portal and carry out the following steps:

1. From the IRIS home page, click on “Ongoing Submissions” sub-tab present under “Submission” tab;

2. Locate the submission mentioned in the e-mail by using the sort or search features described 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 updated or new documents, click on “Documents from Applicant”. Click on “Save and Return” when you are done;
7. 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;
8. Click on the “Declaration and submission” button;
9. If you are sure you want to submit the application, click” **Submit**”, then “**OK**” and then “**Submit**”.

2.12. Respond to a List of Questions (LoQ) request (not applicable for PLM cases)

On receipt of a notification email from EMA regarding a “List of Questions (LoQ)” relating to one of your Ongoing Submissions, after validation and start of procedure, you can upload revised/new documents, but you cannot modify the submission data in the portal. Log into the IRIS portal and carry out the following steps:

1. From the IRIS home page, click on “**Ongoing submissions**” sub-tab present under **“Submission”** tab;
2. Locate the submission mentioned in the e-mail;
3. At the end of the row in the list where your submission appears, click on the drop-down arrow and select “**View/edit**”;
4. Click on “**Documents from Applicant**”; click on **“Save and Return”** when you are done;
5. **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;
6. Click on the “Declaration and submission” button;
7. If you are sure you want to submit the application, click “**Submit**”, then “**OK**” and then “**Submit**”.

Your updated application has now been submitted and will appear in your “**Ongoing Submissions**” list and you will receive an e-mail notification to confirm that you have re-submitted the application as requested by EMA.

2.13. Check the current status of submissions in the IRIS portal

The possible status for the Applicant’s submission (see Table 1. Submission StatusTable 1. Submission Status) are shown in the below table.

Table 1. Submission Status

Submission Status	Notes
Draft	The application is in draft status and can be deleted or submitted (when finalized). Inspection submission cannot be deleted.
In Progress	Application submitted; Case ongoing at EMA
Pending Payment	Pre-payment is required.
Payment Received	Payment received and start of the procedure.
Withdrawal Requested	The applicant has requested a withdrawal, which is being assessed at EMA.
Completed-Positive	Case closed, positive outcome
Completed-Negative	Case closed, negative outcome
Completed-Withdrawn	Case closed as withdrawn, at the applicant's request.
Completed-Cancelled	Inspection request has been cancelled by CHMP/CVMP
Cancelled – payment not received	Payment was not received, and submission is cancelled.
Pending EC decision	PLM procedure with immediate EC decision and pending EC decision
Pending resolution	PLM procedure with pending confirmation of EPAR publication before completed
Under evaluation	PLM procedure under evaluation or in clock stop
Under validation	PLM procedure under validation

2.14. Withdrawal of a submission

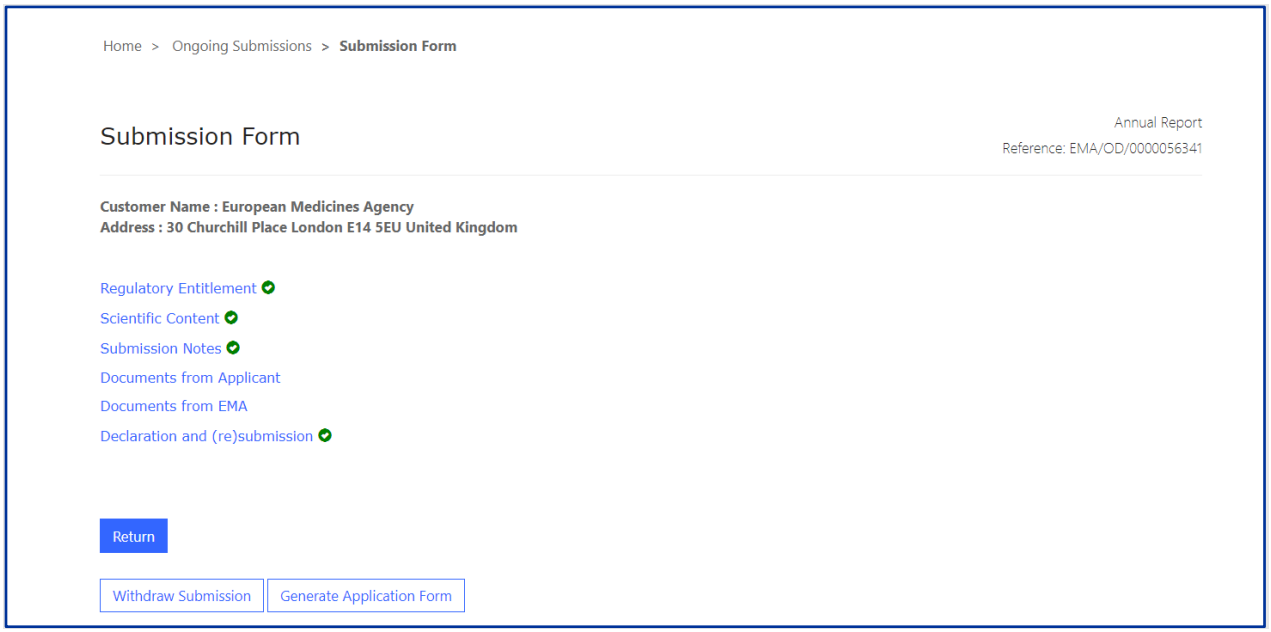
You can only withdraw a submission for the Ongoing applications for which you have a "Manager" role (not if you have a Contributor or a Coordinator role). Please note you cannot withdraw PLM procedures that have received an opinion/notification or have the "Completed" status and parallel distribution notifications for which pre-payment process applies.

1. Click on "**Ongoing Submissions**" sub-tab present under **"Submission"** tab;

2. Find the application you want to withdraw from the list of your “Ongoing Submissions”;
3. Click on the drop-down arrow on the right-hand side of the submission row and select “**View/Edit submission**”, the Submission will open in edit mode.

   Note: Prior requesting the withdrawal for PLM procedures it is mandatory to provide a brief explanation detailing the reasons for the withdrawal of the submission. Select the “Submission details” form, enter the withdrawal reason and click submit. Repeat step 3 before processing with step 4.
4. Click on **“Withdraw Submission”** button present at the bottom as shown in Figure 7. Withdraw a Submission. A confirmation window will appear, confirm the withdrawal request.
5. Please upload any documents that may be relevant to the withdrawal in the “**Documents from Applicant**” section.
6. The status of the submission will change to “Withdrawal Requested” as shown in **“Ongoing Submission”** tab;
7. Once EMA has processed the request of withdrawal, the submission will move to **“Completed Submission**” tab and the status will change to “Completed – Withdrawn”.

Figure 7. Withdraw a Submission



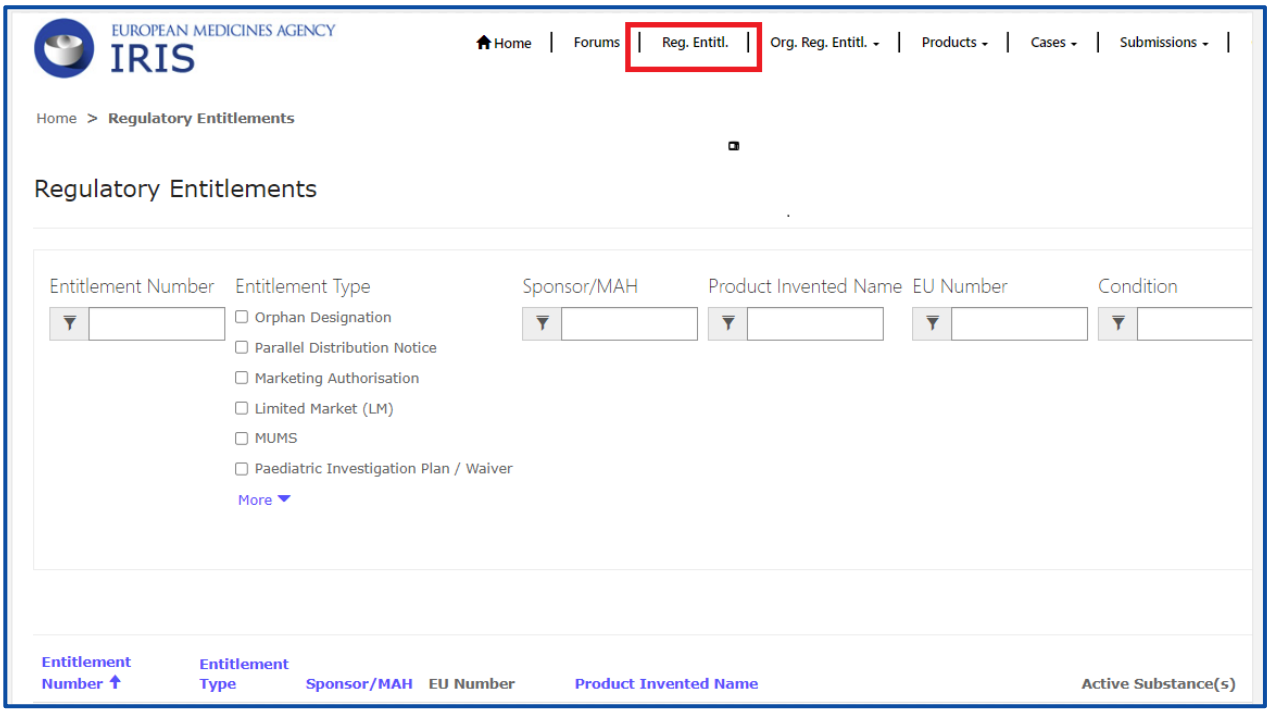
2.15. Regulatory entitlements affiliation

2.15.1. Regulatory entitlements

This tab enables you to see a list of all regulatory entitlements related to the organisation(s) you are affiliated to. It is possible to filter the regulatory entitlements by entitlement number,

entitlement type, sponsor, product name, EU number, and date of decision (see Figure 8. Regulatory Entitlements).

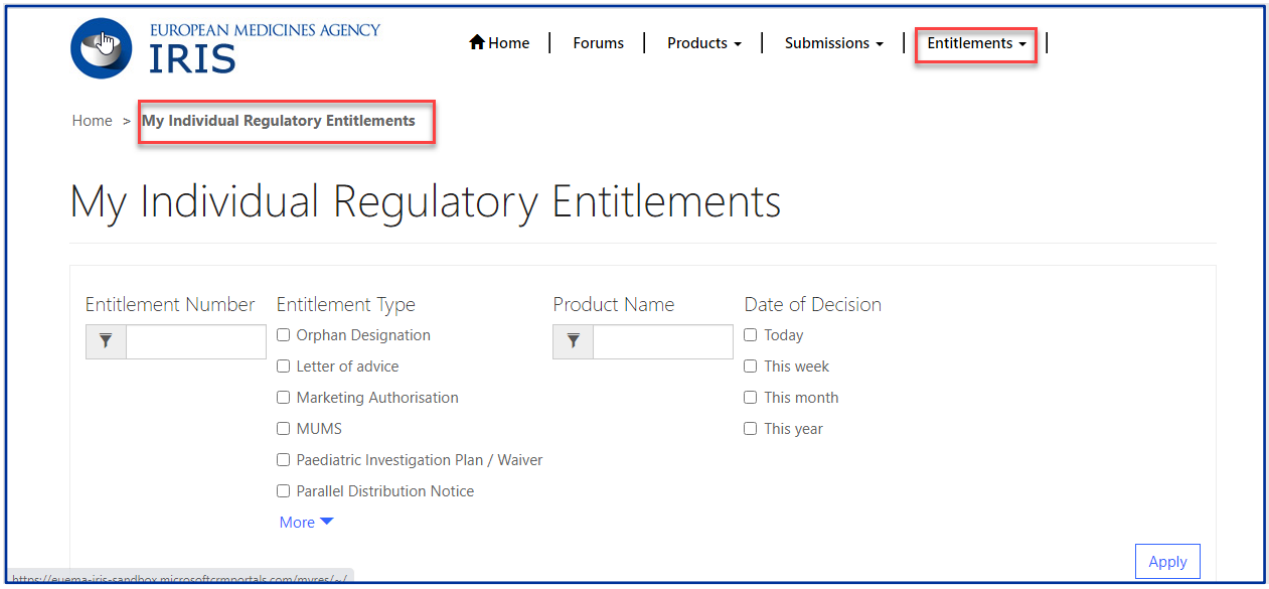
Figure 8. Regulatory Entitlements



2.15.2. My individual regulatory entitlements

The tab enables you to see the list of all regulatory entitlements that were granted as an outcome of submissions created by you. It is possible to filter the regulatory entitlements by entitlement number, entitlement type, product name and date of decision.

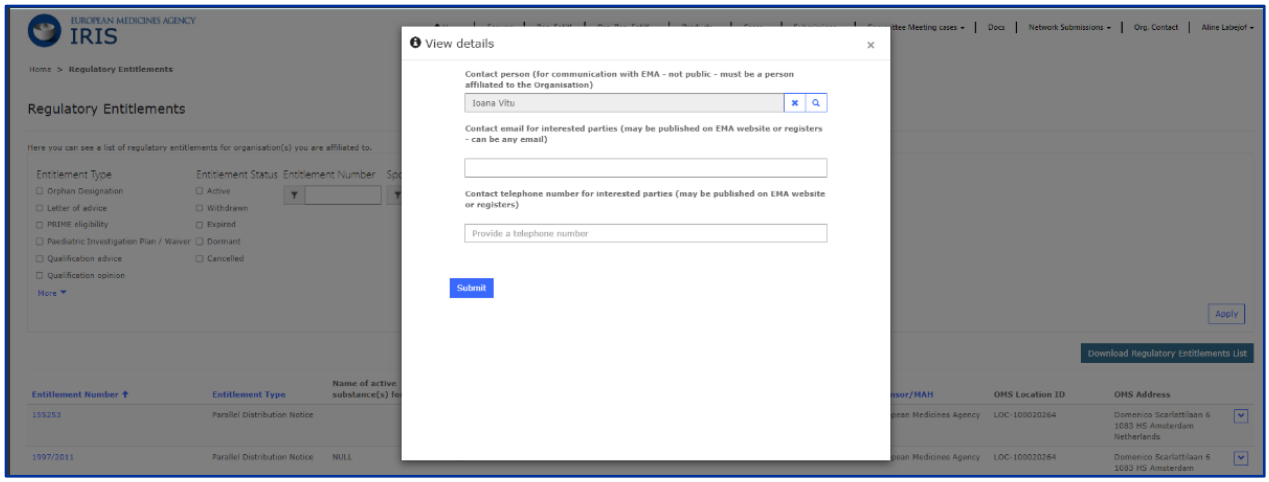
Figure 9. My Individual Regulatory Entitlements



2.15.3. My contact information management

This tab enables you to update the public email address and phone number used for public enquiries, as well as the contact person (not public).

Figure 10. My Contact Information Management



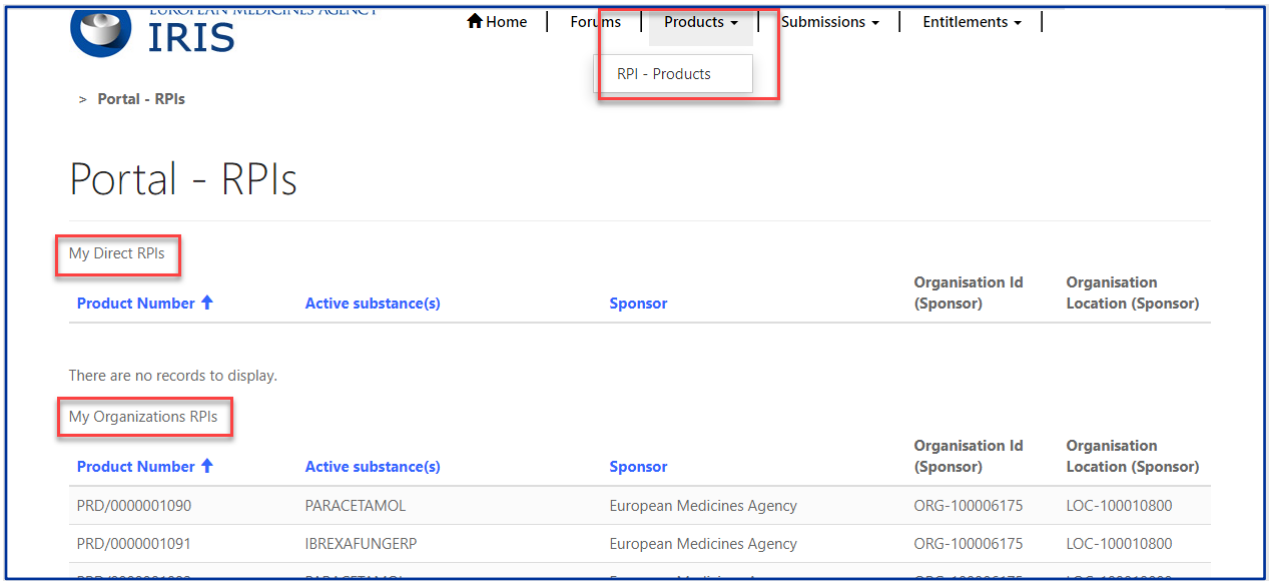
2.16. Products - Research Product Identifiers (RPI)

It is also possible to see all RPIs (Research Product Identifier) for which you are the sponsor, either individually or via an affiliation to one or more companies. Two views are shown (see Figure 11. Product- View of RPI's).

“**My Direct RPIs**", which displays all active RPIs for which you are a direct sponsor.

"**My Organizations RPIs**" shows active RPIs for all organization locations you are affiliated to (in any of the locations).

Figure 11. Product- View of RPI's



3. Orphan submissions

Domain applicability: human

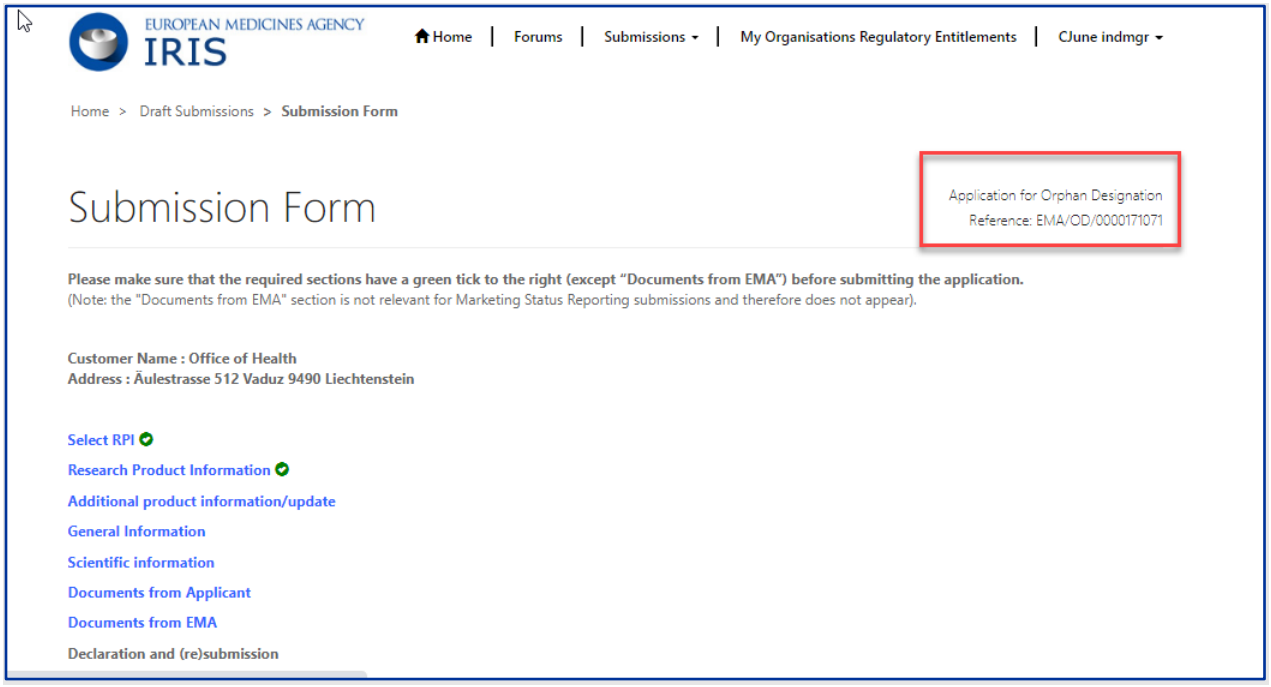
For general information on orphan designation and allied procedures, please consult the Orphan Designation page of the EMA website. For specific information on how to prepare a specific Orphan submission, including how to prepare the Scientific Document, please see the specific sections on the Orphan Designation page.

3.1. Create an application for orphan designation

In addition to the steps in the general procedure described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)", please note the specific issues for Orphan Designation below:

The reference number will have "OD" in it (e.g. EMA/OD/0000001234) for your draft submission displayed on the upper right-hand side of the "Portal – New Submission" screen (see Figure 12. Application for orphan designation, main screen).

Figure 12. Application for orphan designation, main screen



The sections (tabs) of the submission are: "**General Information**" and "**Scientific Information**". Complete (at least) the mandatory fields marked with a red asterisk "*" and click "**Save and Return**" (N.B. in the prevalence box, enter the prevalence per 10,000 persons in the EU population, as a single number (normally, from 0 to 5.0) and NOT in the form of a ratio). See Figure 12. Application for orphan designation, main screen.

3.2. Request a pre-submission meeting (for OD)

IMPORTANT: Before creating a request for a **pre-submission meeting**, please create the draft submission for the orphan designations as described above. This must be left as a draft, without submitting it for the moment. Any documents should be uploaded within the draft submission for orphan designations, not in the pre-submission meeting request. The number of the draft request for orphan designation should be referenced in the pre-submission meeting request;

1. Select "Request for Pre-Submission Meeting" as submission type;
2. Click "**Continue to submission form**" and a number (e.g. EMA/OD/0000001234) for your draft submission is displayed on the upper right-hand side of the "Portal – New Submission" screen (N.B. It is a good idea to take note of the reference number created);
3. Back in the Submission Form screen, click on "**Submission Details**", enter the information that you want the EMA Orphan Medicines team to know and click "**Save and Return**";
4. Follow steps 13 and 14 from Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)" above;

5. Your request for a Pre-Submission Meeting has now been submitted and will appear in your "**Ongoing Submissions**" list.

3.3. Request an appeal (of a COMP opinion)

In addition to the steps in the general procedure as described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)", note the following:

1. As submission type, click on "**Appeal**" and then click "**Select**";
2. Click "**Create and Next**" – you will see the message "processing…" for a short while;
3. Click "Continue to submission form";
4. Click on "**Start Appeal**" and the "View Start Appeal Form" screen appears;
    a. Click on the magnifying glass to select the procedure to be appealed – only cases which have been submitted and are currently in ongoing status are displayed;
    b. Click on one of the procedures listed then click Select" and "Submit";
5. From the "**Submission Form**" screen, click on the "**Ground of appeal**" Section; fill in the relevant information in the mandatory "Applicant's grounds for appeal *" box and click "**Save and Return**".

3.4. Submit an annual report for an orphan designation

The process for submitting Annual Reports has now been simplified. Applicants are not requested to compile and submit the previous PDF form, which has been removed from the website. It is now only necessary to complete the information in a few specific data fields in IRIS. Uploading additional supporting documents is still possible but not mandatory.

In addition to the steps in the general procedure as described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)", note the following additional points:

1. As submission type, click on "**Annual Report**" and then click "**Select**";
2. Click "Create and Next" and then click "Continue to submission form";
3. Click on "**Regulatory Entitlement**" (a generic term for a right granted to a sponsor such as an orphan designation or a transfer of orphan designation);
    a. In the "Regulatory Entitlement" window, **click on the magnifying glass symbol** to search through the existing orphan designations for your organisation;
    b. Select the orphan designation for which you are submitting the Annual Report and click "**Save and Return**". If you cannot find your orphan designation, please contact the Orphan medicines office;

4. Click on "**Scientific content**" and complete the information in the data fields, amending the prefilled fields where appropriate. All fields with an asterisk are mandatory. Click on "**Save and Return**";
5. Back in the Submission Form screen, click on "**Submission Notes**", enter any additional free-text information that you want the EMA Orphan Medicines team to know and click "**Save and Return**".

3.5. Other post-designation procedures for orphan-designated products

All other post-designation procedures for existing orphan designations should be submitted via IRIS, choosing the appropriate procedure type. These include:

1. Submission of a report for the Maintenance of the Designation Criteria at Marketing authorisation (or extensions);
2. Submission of a report for a Review of the Designation criteria after 5 years;
3. Request for an Amendment of an existing Orphan designation (to change the condition);
4. Request to transfer an Orphan Designation;
5. Request of removal of an Orphan designation from the EC Orphan register;
6. Change of name and/or address of the Sponsor of an orphan designation.

The procedures are very similar to the general procedure as described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)"Create a new submission (general procedure for all submission types, except PLM procedures), and are not listed for brevity. For general information on these submission types, see the Activities after orphan designation webpage in the main EMA website.

3.6. How to check if an orphan drug sponsor (Location of an organisation) has associated regulatory entitlements

Go to https://ec.europa.eu/health/documents/community-register/html/reg_od_act.htm?sort=a and search for EU product e.g. EU/3/19/2181.

Click on the EU number from the search results. For field "Sponsor" -Organisation name and location will be mentioned. This location has Regulatory entitlements and the same can be selected in IRIS while drafting a form.

4. Scientific Advice

Domain applicability: human & veterinary

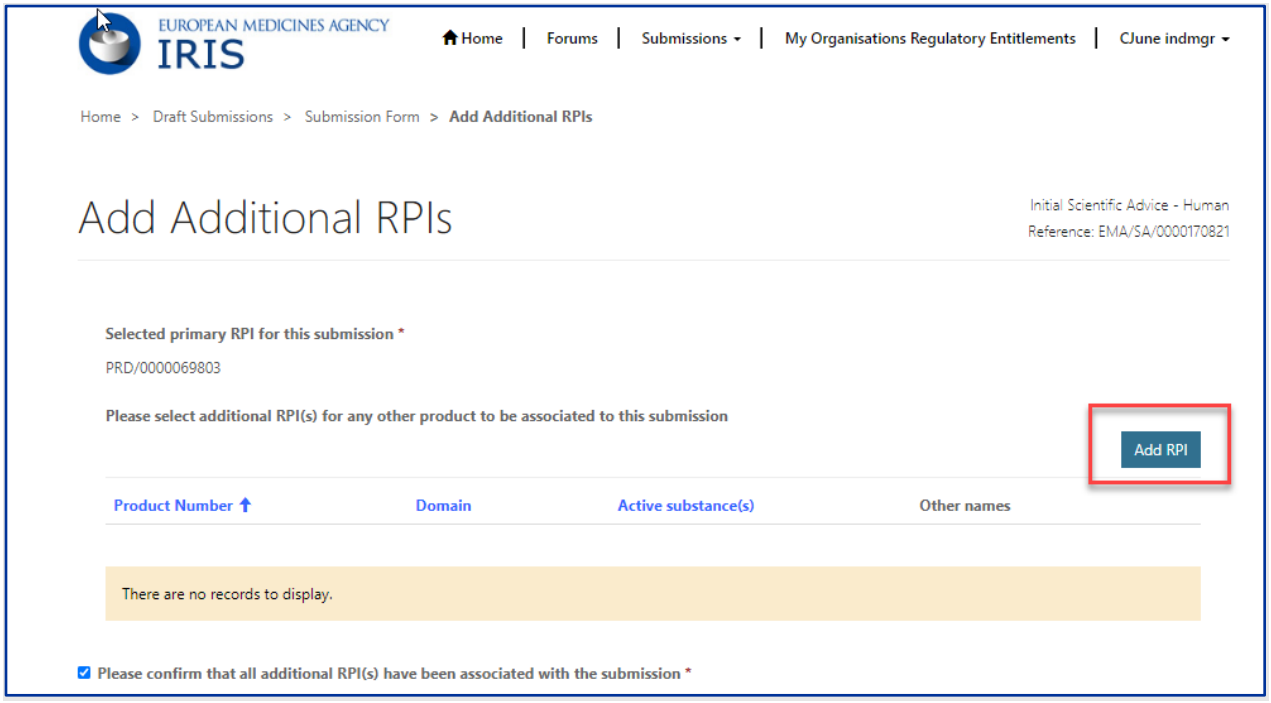
For general information on Scientific Advice, please consult the Scientific advice and protocol assistance section of the EMA website. For specific information on how to prepare a Scientific Advice submission, including the Scientific Document (Briefing Document), please see the How to submit a scientific advice or protocol assistance request section on the EMA website.

4.1. Create an application for an initial scientific advice (Human)

In addition to the steps in the general procedure as described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)", select **"Initial Scientific Advice-Human"** as the submission type. Note the following additional points:

- The reference number will contain SA (e.g. EMA/SA/0000001234) for your draft submission displayed on the upper right-hand side of the "Portal – New Submission" screen;
- There is a list of eleven steps (tabs) starting with "Administrative Information" and ending with "Declaration" relating to the SA Application displayed on the left-hand side of your screen; the two sections "**Administrative Information**" and "**Select Primary RPI**" must be completed, before the other sections (tabs) become available (they turn from grey to blue);
- In section "Administrative information" please specify the "Type of Request" to flag if your submission is related to a Standard SA request of if it is a SA request related to a declared or potential public health emergency (see Section 4.2).
- You can optionally select additional (secondary) RPIs to link to your procedure by clicking on "**Add Additional RPIs**" (see Figure 13. How to include additional RPIsFigure 13. How to include additional RPIs). Note that only RPIs "owned" by the same applicant can be added;
- You can also add **"Submission Notes"** with additional information in scientific advice forms. This field can be used to specify why the procedure qualifies for not following standard deadlines (e.g., COVID rapid request).
- Some sections/tabs may not be applicable, e.g. "Parallel Consultation EMA/EUnetHTA"; however, at least the mandatory field(s) marked with a red asterisk "*" should be completed.
-

Figure 13. How to include additional RPIs



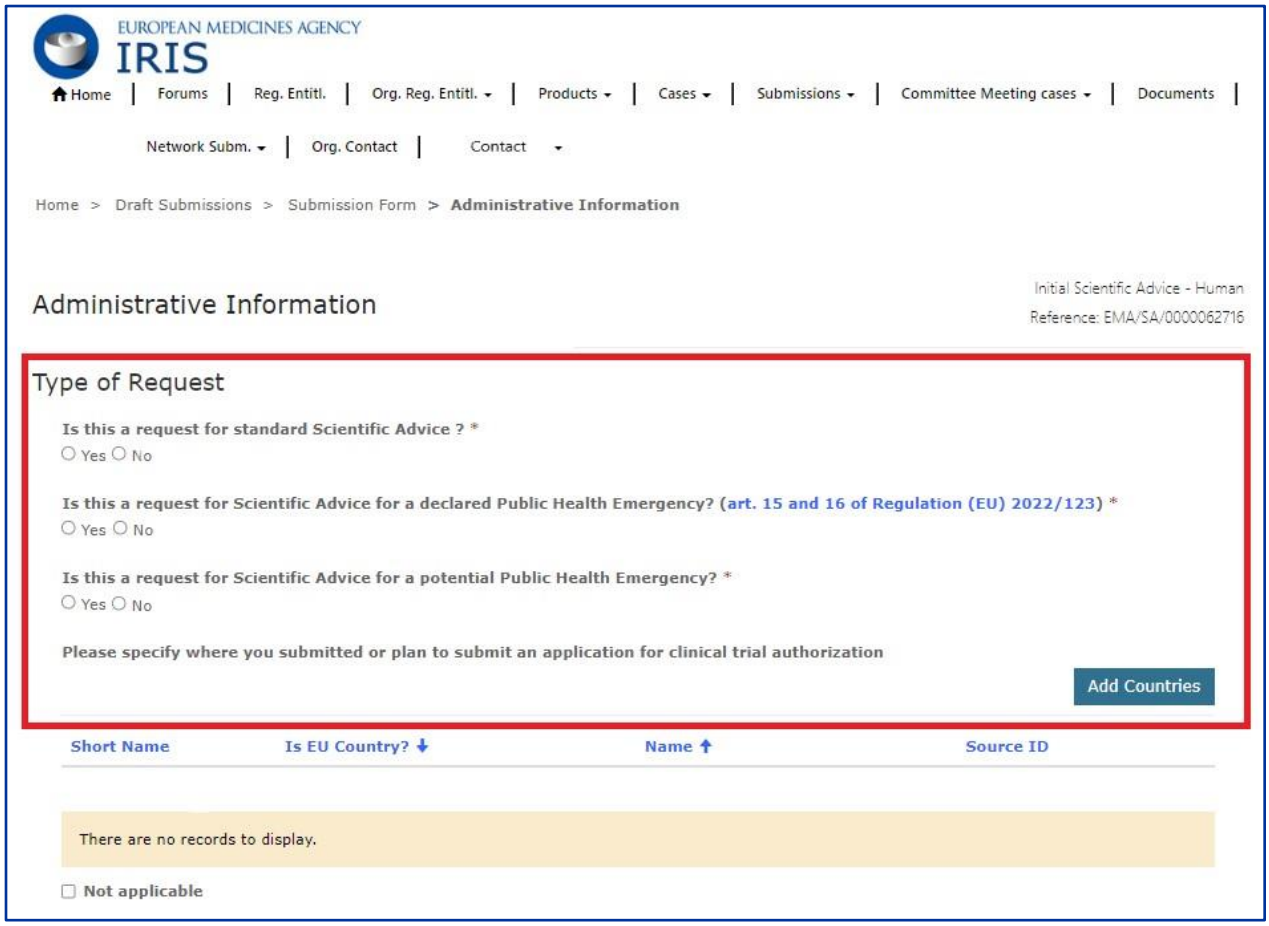
4.2. Create an application for an initial scientific advice (Human) for medicines intended to address a declared public health emergency or a potential future emergency

The Emergency Task Force (ETF) is a multidisciplinary expert group established within the EMA by Regulation (EU) No 2022/123, to be convened in preparation for and during a public health emergency (PHE). As such, the ETF is delegated (1) to provide scientific advice on medicinal products targeting the PHE and (2) to provide scientific advice on medicinal products targeting a potential future PHE. A scientific advice can cover quality, non-clinical and clinical aspects of product development including clinical trial protocols for both types of scenarios mentioned.

For submitting such SAs, follow the steps in the general procedure as described in Section 2.3 “Create a new submission (general procedure for all submission types)”, selecting “Initial Scientific Advice-Human” as submission type.

In the “Administrative information form”, the section “Type of Request” contains questions that help differentiate between standard SAs and SAs on medicinal products addressing a declared or potential PHE (see Figure 14. Different types of SA):

Figure 14. Different types of SA



If the submission is related to:

1. a request for a standard scientific advice, meaning not related to a product or clinical trial targeting a declared or potential PHE, answer with “Yes” to “Is this a request for standard Scientific Advice ?” These applications will be assessed by the SAWP.
2. a declared PHE, answer with “Yes” to “Is this a request for Scientific Advice for a declared Public Health Emergency? (art. 15 and 16 of Regulation (EU) 2022/123)”. A public health emergency can be declared by either WHO or the European Commission. Select the specific PHE from the drop-down menu in the subsequent question “Please specify the Public Health Emergency”. These applications will be assessed by the ETF.
3. a pathogen which has the potential to cause a PHE, answer with “Yes” to “Is this a request for Scientific Advice for a potential Public Health Emergency?”. Specify the pathogen by choosing from the drop-down menu in the subsequent question “Please specify the pathogen or agent” (e.g., Ebola virus, Zika virus, Chikungunya virus). The ETF will provide advice on the pathogens listed in the drop-down menu. However, the list is not exhaustive and for this reason the term “Other pathogens/threats” is included in the drop-down menu. Applicants should select “Other pathogens/threats” when the pathogen they are seeking advice on is not listed in the menu, but it has the potential to cause a future emergency. A free text box will then appear for applicants to list a specific pathogen, either of viral or bacterial origin,

which have the potential to cause a future emergency. EMA will consider on a case-by-case basis whether these applications can be assessed by the ETF or by the SAWP.

The question “Please specify where you submitted or plan to submit an application for clinical trial authorization” aims at identifying the member states where the Applicant intends to submit or has submitted a clinical trial application. This will allow the Agency to involve in the scientific advice assessment process the representatives of the clinical trial authority of the MS responsible for the trial authorisation. Click on “Add Countries” and select from the displayed list of countries the country where clinical trials related to the current SA submission have been submitted or are intended to be submitted.

4.3. Create an application for other scientific advice procedures

4.3.1. Initial scientific advice – veterinary

Follow the steps in the general procedure as described in Section 2.3 “Create a new submission (general procedure for all submission types, except PLM procedures)”, selecting **“Initial Scientific Advice-Veterinary”** as submission type.

4.3.2. Initial protocol assistance

Protocol Assistance is Scientific Advice for designated orphan medicinal products. In addition to questions on quality, safety and clinical aspects, questions on significant benefit may also be discussed.

In addition to the steps in the general procedure as described in Section 2.3 “Create a new submission (general procedure for all submission types, except PLM procedures)”, note the following additional points:

1. The applicant must be the same as the Orphan Designation Sponsor;
2. While drafting this type of application, applicant cannot proceed further than **“Orphan Designation”** until an existing orphan designation (or at least a positive opinion date), for a product belonging to the same customer, has been selected first and associated to the submission. It is possible to submit the application after a COMP Opinion has been adopted, but before the formal Decision by the European Commission, by choosing the ongoing procedure instead of an Orphan Designation; however, the Decision must be adopted before the start date of the Protocol Assistance procedure;
3. Please note that several fields will be prepopulated from the associated orphan case and cannot be changed. These include the RPI and the medical condition (which must be the same as the orphan condition in the designation, by law).

4.3.3. Initial qualification procedure

In addition to the steps in the general procedure as described in Section 2.3 “Create a new submission (general procedure for all submission types, except PLM procedures)”, note the following additional points:

Select “Initial Qualification Procedure” as submission type.

4.3.4. Transfer a scientific advice

Owners of Scientific Advice regulatory entitlements (Letters of Advice) are now able to transfer regulatory entitlements automatically to another owner, similarly to the RPI transfer process. Only scientific advice entitlements can be transferred with this new automated process, which is necessary when the applicant for a follow-up scientific advice or protocol assistance is not the same as the initial advice.

In addition to the steps in the general procedure as described in Section 2.3 “Create a new submission (general procedure for all submission types, except PLM procedures)”, note the following additional points:

Select “Transfer a scientific Advice” as submission type.

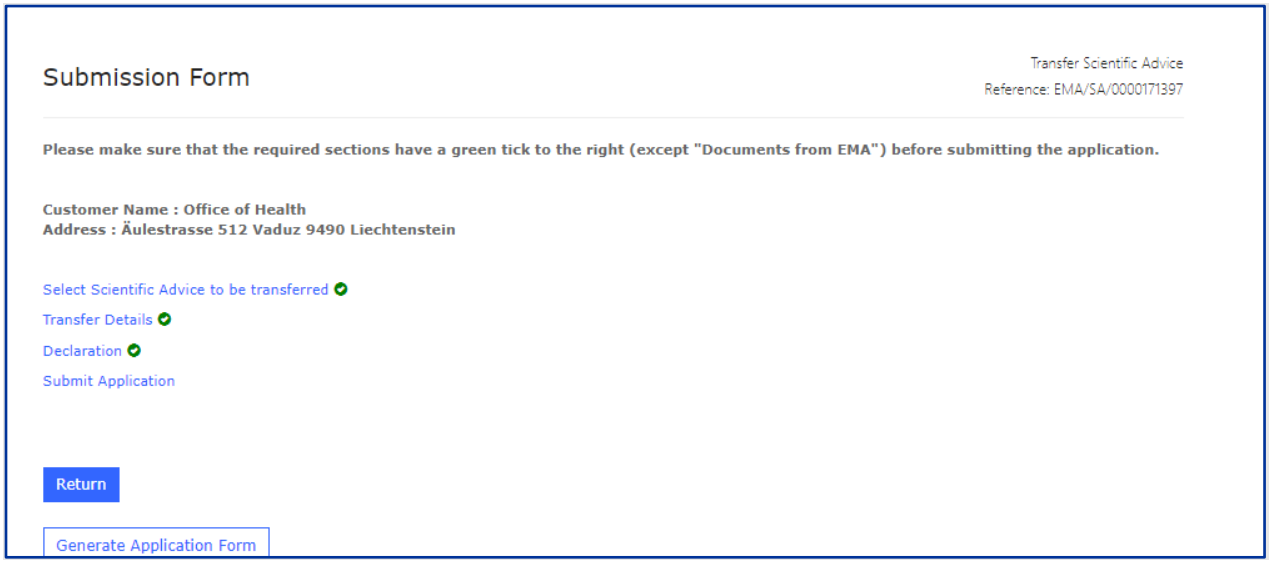
The reference number will contain SA (e.g. EMA/SA/0000001234) for your draft submission displayed on the upper right-hand side of the “Portal – New Submission” screen;

The following four tabs will appear as shown in Figure 15. Transfer Scientific Advice:

1. **Select Scientific Advice to be transferred**: Click on the tab and a new screen will open. Select the desired submission to be transferred, using the search icon option if necessary, and click on “**Save and Return**”;
2. **Transfer details:** Click on the tab and a new screen will open. Here the current sponsor details will be shown in “**read-only**” mode and below you can add the **“New Sponsor Type**” as Organisation/Individual, then select the “**New Organisation**”. The organisation address will be shown in read-only mode. Once all details have been added, click on “**Save and Return**”.
3. **Declaration**: Click on the tab and a new screen will open. Select the checkbox for the declaration and click on “**Save and Return**”;
4. **Submit Application**: Once all the above tabs have been filled and green check marks show, the “**Submit Application**” button becomes enabled. Click on it and a new screen opens, select the checkbox asking for confirmation, and click on “**Submit Button**” box. A pop-up window will appear, giving you a final opportunity to go back and check that all the details have been entered correctly (“Review Application”), or continue and submit.

Once submitted, the Submission will be shown in “**Outgoing**” tab and the product will be updated with new sponsor type as mentioned while filling the form.

Figure 15. Transfer Scientific Advice



4.3.5. Clarification on scientific advice

Users can request clarification on a closed Scientific Advice case related to an Initial Scientific Advice or Follow Up Scientific Advice by submitting a request "Clarification on scientific advice" in IRIS.

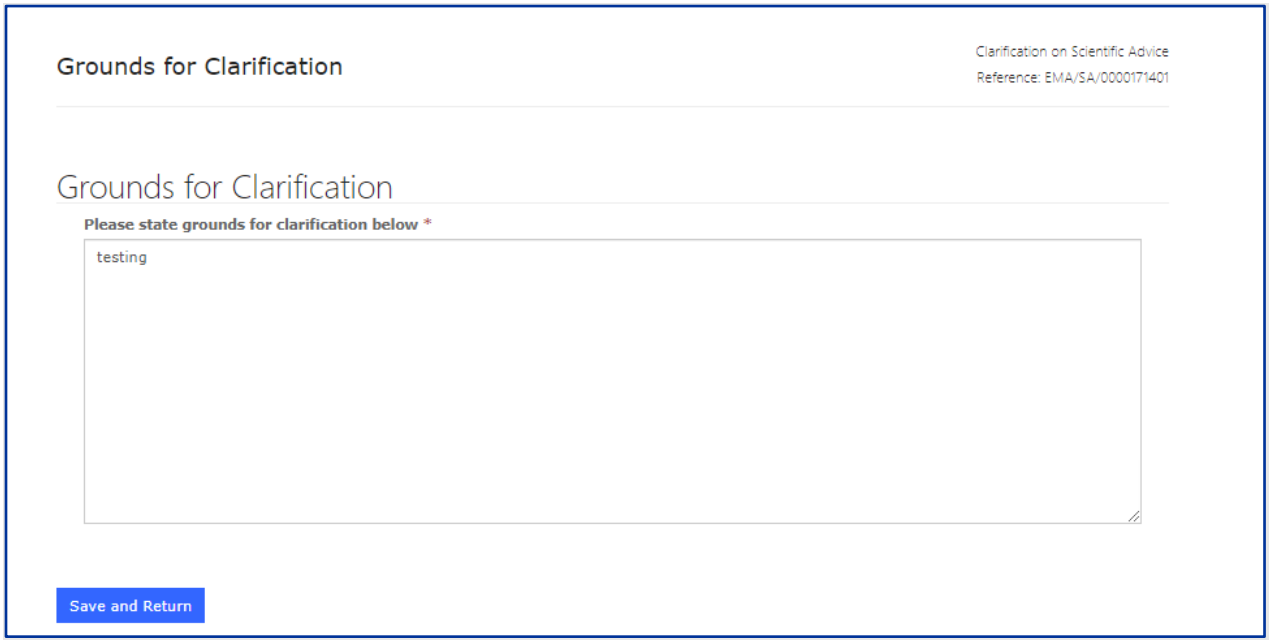
In addition to the steps in the general procedure as described in Section 2.3. “Create a new submission (general procedure for all submission types, except PLM procedures)”, note the following additional points:

Select **“Clarification on scientific advice”** as submission type. The reference number will contain SA (e.g. EMA/SA/0000001234) for your draft submission displayed on the upper right-hand side of the “Portal – New Submission” screen;

The following six tabs will be shown:

1. **Select previous Advice:** Click on the magnifier of this field, and a new screen will open. Select the desired submission. Click on “**Save and Return”**;
2. **Grounds for Clarification:** Once a previous advice is selected, this tab is enabled for you to add the notes (Figure 16. Adding notes for clarification). Once added, click on “**Save and Return”;**

Figure 16. Adding notes for clarification



3. **Documents from Applicant:** It is possible to add documents under this tab**.** Select that declaration confirming documents have been attached and click on "**Save and Return**";
4. **Documents from EMA:** Can be skipped as part of drafting process;
5. **Declaration**: Click on this tab, and a new screen appears. Select the checkbox for the declaration and click on "**Save and Return**";
6. **Submit Application**: Once all the above tabs have been filled and green check marks show, the "**Submit Application**" button becomes enabled. Click on it and a new screen opens, select the checkbox asking for confirmation, and click on "**Submit Button**" box. A pop-up window will appear, giving you a final opportunity to go back and check that all the details have been entered correctly ("Review Application"), or continue and submit.

Once submitted, the Submission will be shown in "**Outgoing**" tab and the product will be updated with new sponsor type as mentioned while filling the form.

4.3.6. Scientific advice FAQ

Frequently asked questions related to Scientific Advice can be found in "Forums" tab in **IRIS** website.

5. ITF briefing meeting requests

Domain applicability: human

In addition to the steps in the general procedure as described in Section 2.3. “Create a new submission (general procedure for all submission types, except PLM procedures)”, note the following additional points:

1. Select “**ITF Briefing Meeting Request**” as submission type;
2. The section “**Documents from applicant**” is available to upload any supporting documents;
3. The section “Documents from EMA” is where you can find any documents provided by EMA to you, including the minutes from the meeting.

6. Marketing status

Domain applicability: human

Three submission types can be used to address the market changes in IRIS portal. They are listed below.

Marketing Status Notification (Single) - this function allows to report the same change in marketing status affecting one or more presentations of a CAP (centrally authorised product) in one or more MS (e.g. placing on the market of 3 presentations in 5 Member States on the same day). Please follow the steps mentioned in 6.1.

Marketing Status Notification (Bulk Upload) - this function enables to report several different changes in marketing status affecting one or multiple presentations in one or multiple MS, by uploading an excel spreadsheet (e.g. placing on the market of presentation B in CZ, AT and NL + marketing cessation of presentation A in IT on different dates). Please follow the steps mentioned in 6.2.

Marketing Status Withdrawal Notification - this function allows to report:

- A request for **withdrawal of the central marketing authorisation** of your product (This would not replace the formal request to send to the European Commission, see question *How should I request the withdrawal of my central marketing authorisation?)*
- a **decision not to apply for the renewal of the marketing authorisation**
- a **permanent marketing cessation** affecting all presentations of a medicinal product in all MS. Of note, if the marketing authorisation is not withdrawn, it will automatically expire after 3 years of non-marketing under the sunset clause provision (see *Q&A on sunset clause provision*).

Table 2. Examples on most appropriate paths to report Marketing Status and Withdrawal

Example	
How to report the market launch of 2 presentations of the medicinal product in ES, FR and IT	Marketing Status Notification (Single) Alternatively, you can also use Marketing Status Notification (Bulk)
How to report **temporary** marketing cessation of all/some presentations in some EU MS	Marketing Status Notification (Single) Alternatively, you can also use Marketing Status Notification (Bulk)
After the launch of the tool, how to report the current marketing status of all presentations of medicinal product in all EU/EEA MS.	Marketing Status Notification (Bulk) Alternatively, you can also use Marketing Status Notification (Single)

Example	
How to report the intent to withdraw the marketing authorisation of a medicinal product for commercial reasons	Marketing status Withdrawal notification
How to report the **permanent** cessation of all presentations in all EU/EEA MS. (Sunset clause will be triggered)	Marketing status Withdrawal notification
How to report the **temporary** cessation of all presentations in all EU/EEA MS. (Sunset clause will be triggered)	Marketing Status Notification (Single) Alternatively, you can also use Marketing Status Notification (Bulk)

6.1. Marketing status notification (single)

In addition to the steps in the general procedure as described in 2.3. Create a new submission (general procedure for all submission types), select **"Marketing Status Notification (Single)"** and note the following additional points:

1. Starting with clicking **"Select Authorised Product"** as the other steps become available after selection of the product (Figure 17. Marketing Status Single NotificationFigure 17. Marketing Status Single Notification);

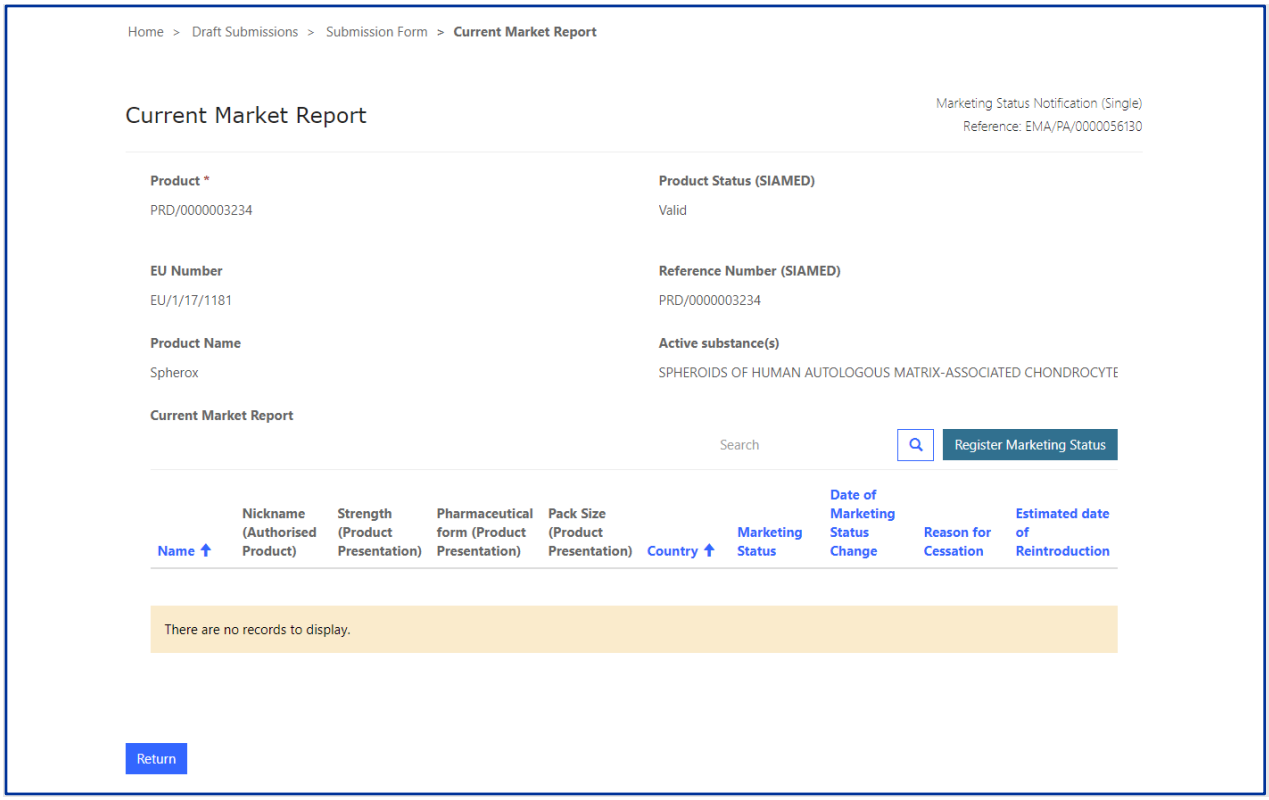
Figure 17. Marketing Status Single Notification

2. Click on the search icon under **“Authorised Product”.** A list will appear, which includes all products associated to the selected organisation. Select one, then click on “Save and Return”. Once the record is saved, the system will auto-populate details like ’Product Status’, ‘EU number’, ‘Reference number’, ‘Active Substance(s)’, ‘Product Name’, when you revisit the **“Select Authorised Product”** tab**.**

Please note that once you select an authorised product and click on 'Save and Return', you can no longer change the product in this submission. If you need to select a different authorised product, you can do so by starting a new submission. In this case, you need to delete the submission yourself present under draft submission by following steps mentioned in section 2.7.

3. Click on the section **“Register Marketing Status”-** all product presentations are shown, for the selected ‘Authorised Product’ in the page “Current Market Report”. Please note if you are doing this for the selected product the first time, you will not see any presentation listed. You can add the relevant product presentation(s), member state(s) and Marketing availability by clicking on the ‘**Register Marketing Status’** button, as shown in Figure 18. How to add Product Presentations.

Figure 18. How to add Product Presentations



All fields marked with red asterisk are mandatory to fill (Figure 19. Adding product presentation, Marketing Status & Member states). This page is divided into 3 sections.

Marketing status - The fields present under this section are dynamic and will change based on selection of value in the field “Marketing Status”:

- **Marketing Status = ’Marketed’**: Select this field to report the marketing of one/more presentation(s) of the medicinal product in one or more Member State(s) of the Union. The user needs to specify the ‘Date of Marketing Status Change’.

  Please note: A 'Marketed' product may experience a potential or actual shortage as per the shortage definition in Regulation (EU) 2022/123. In this case the marketing status should remain as 'Marketed' in IRIS and the shortage should be reported via the European Shortages Monitoring Platform (ESMP).

- **Marketing Status = ’Temporarily Unavailable’**: Select this field to report that one/more presentation(s) is temporarily ceased to be placed on the market as per Article 13(4) of Regulation (EC) No 726/2004 in one or more Member State(s). Then, ‘Date of Marketing Status Change’, ’Reason of cessation’, ‘Estimated date of Reintroduction’, ‘Does cessation lead to Shortage’ become **mandatory**.

  Please note: Please indicate 'Yes' in the field 'Does cessation lead to Shortage?’ if the reported temporary cessation causes a potential or actual shortage of this temporary ceased presentation or any other presentation on the market. In this case the MAH needs to submit the shortage notification via the ESMP to EMA.

- **Marketing Status = ’Not Marketed’**: Select this field to report that one/more presentation(s) change the status to permanent cessation as per Article 13(4) of Regulation (EC) No 726/2004 in one or more Member State(s). Then, ‘Date of Marketing Status Change’, ’Reason of cessation’, ‘Does cessation lead to Shortage’ become mandatory and have to be specified by the user to save the details.
  Please indicate 'Yes' in the field 'Does cessation lead to Shortage’ if the reported permanent cessation causes a potential or actual shortage of any other presentation still on the market.

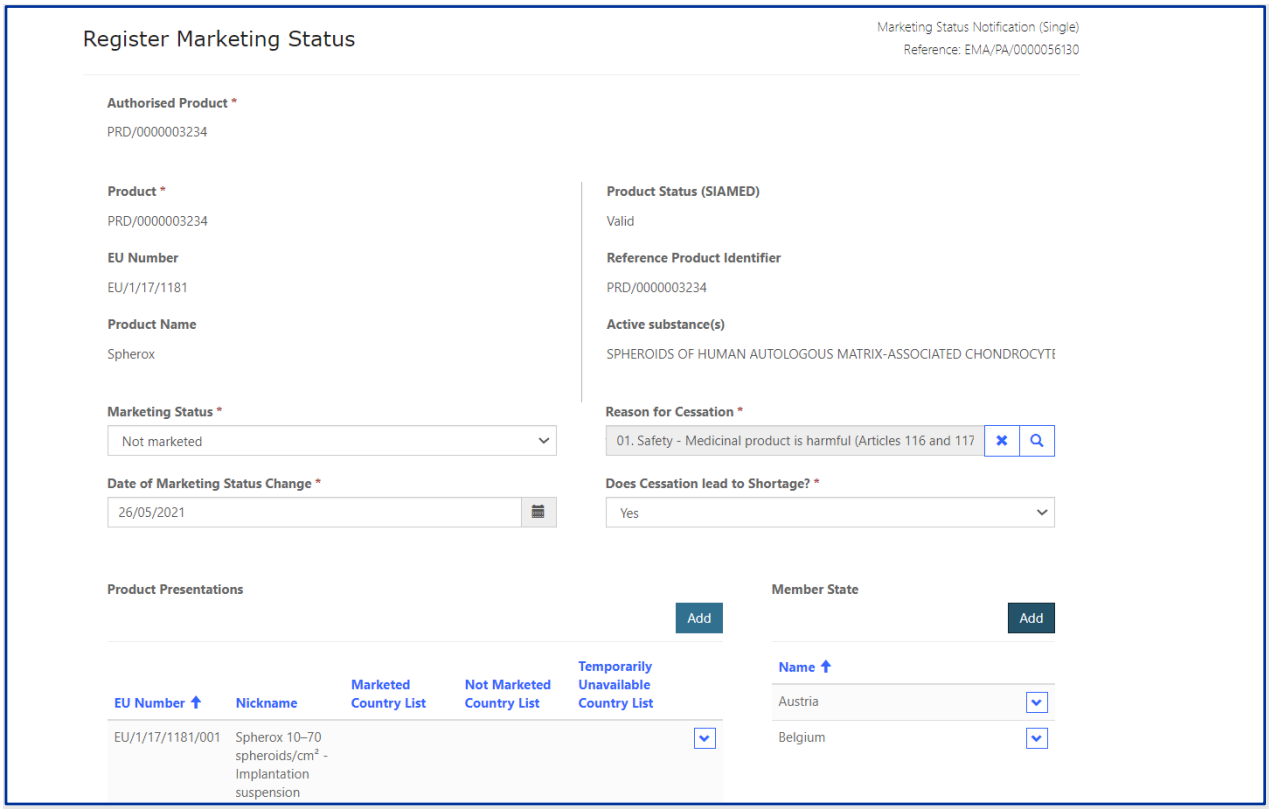
  Please note that the reporting of changes to the marketing status and in particular withdrawn products/presentations in IRIS should not be understood as meeting the obligations to report in parallel marketing cessations at national level to the relevant EU national competent authorities. The MAH should check with the EU national competent authorities the process to inform them accordingly.

- **Marketing Status = 'Never Marketed'**: Select this field to report that one/more presentation(s) of the medicinal product has/have never been marketed in any Member State(s) of the Union.

Please refer to regulatory guidance for [Notifying-change-marketing-status]

- **Product Presentations** - Single or multiple product presentations can be added by clicking on the 'Add' button present under 'Product Presentations'.
- **Member State** - presentations can be marketed in different countries, single or multiple countries can be selected here.

Figure 19. Adding product presentation, Marketing Status & Member states

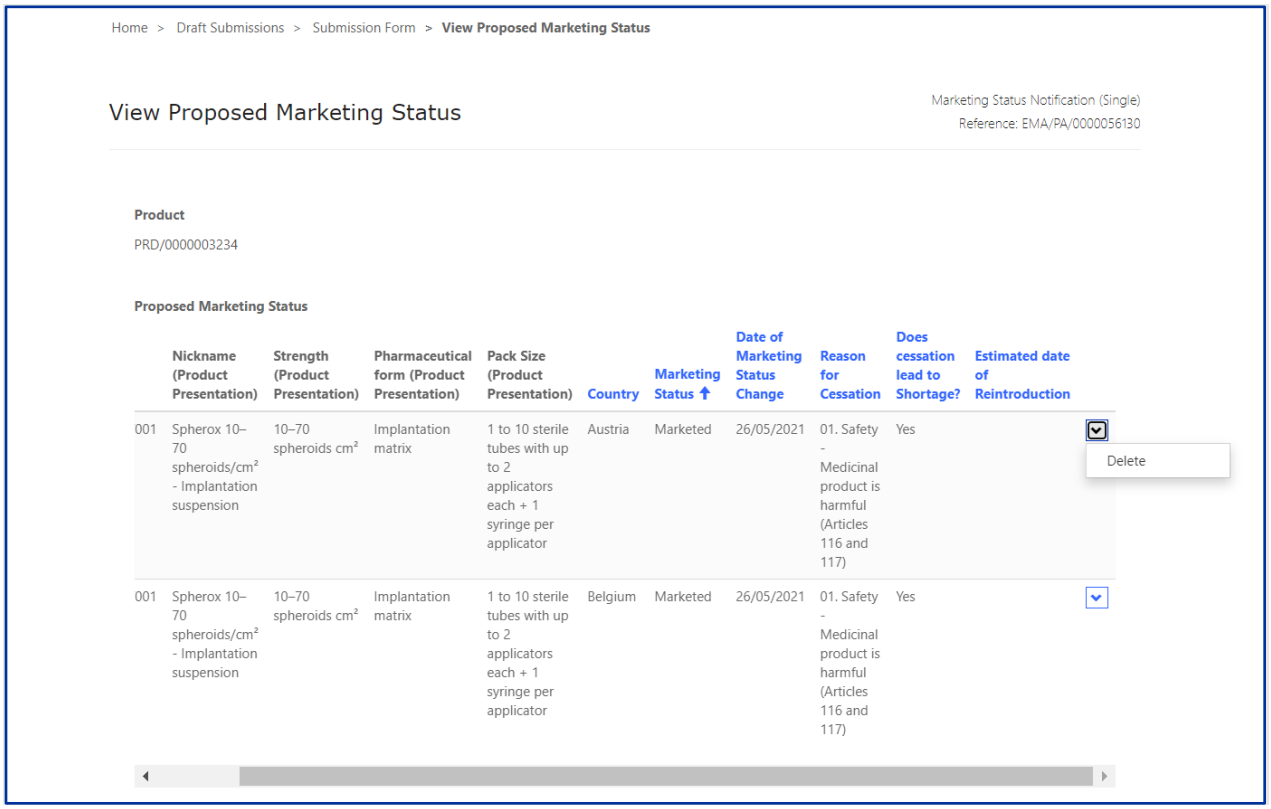


a. Click **'Have you completed Marketing Status Registration 'Yes/No** at the bottom of the page. It is possible to add a new Marketing Status for different presentations by clicking No and then '**Save and return'**. This will allow you to start again on point 3 and add a new Marketing Status for different presentations/Member states. This can be repeated as many times as needed.

b. Once you have completed the Marketing Status Registration, click Yes and then click on '**Save and return'** to go back to the previous section. Please note that in 'Current Marketing Status' form, you will not see any of the presentations just added, those will be showing in section **'View Proposed Marketing Status'.**

4. Click on **'View Proposed Marketing Status'** to view the recently added changes in Marketing status pending to be submitted. This section will list all the presentations and their marketing status in the countries selected in Section **'Register Marketing Status'**. You can also delete presentation for a specific member state by clicking on the v-shaped arrow as shown in Figure 20. Viewing proposed presentations below. Click on '**Return'** after checking all information;

Figure 20. Viewing proposed presentations



5. After completing the steps above, click on '**Declaration'**, confirm the declaration, click Save and Return and submit your application in the '**Submit Application'** section. You will receive a confirmation email on the successful submission.

6. Your submission is shown in the "**Submissions/Ongoing**" sub-tab. After the case (procedure) is automatically processed by the IRIS system, the submission will be moved to the "**Submissions/Completed'** tab. You will receive a confirmation email of the completion of the procedure. Please raise a ticket via the EMA Service Desk by selecting service as '**IRIS'** in case of facing any issues.

6.2. Marketing status notification (bulk upload)

In addition to the steps in the general procedure as described in 2.3. **Create a new submission (general procedure for all submission types)**, select **"Marketing Status Notification (Bulk Upload)"** and note the following additional points:

Select the Authorised product in the section **"Select Authorised Product"**, click **'Save & Return'**.

Click on **"Download Current Marketing Status"** section (Figure 21. Download Excel). All product presentations associated with the product are now displayed in a table; to download the presentations in an Excel file, click on the '**Download'** button. Once the file is downloaded, click on '**Return'** to go back to the main page.

You can then update the data in the file as per your needs. Please make sure that you delete the rows where no changes are required. Also note, all presentations shall belong to same authorised product selected in beginning of the submission.

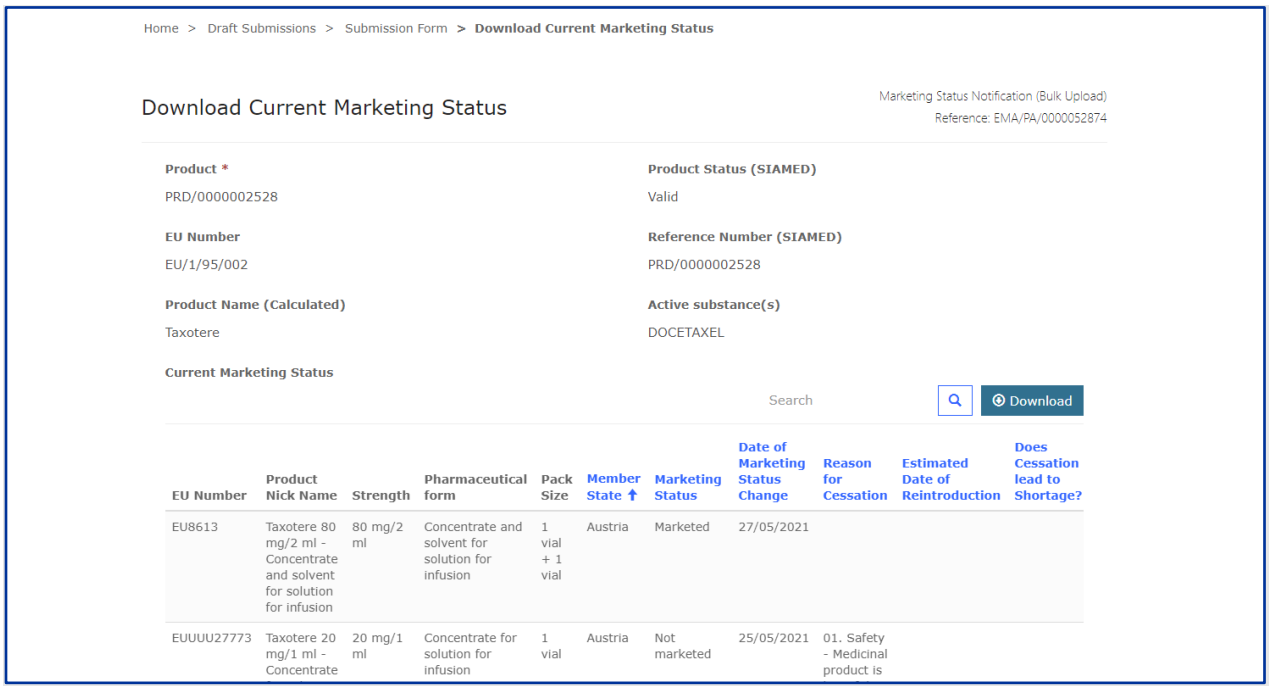
Please note that the values in each column must be provided in a standardised format; refer to Table 3. Format/Values for Fields in csv for the correct format and values to avoid validation failures. The order of the columns should also be maintained, and the headers should not be modified.

Table 3. Format/Values for Fields in csv

Data columns	Format and allowed values
Marketing Status	Marketed Not marketed Temporarily unavailable Never marketed
Date of Marketing Status Change (format)	Excel will apply local time and date format to the Excel file with current marketing status.
Reason for Cessation	Any conditions as per Art. 21, 22 not fulfilled (e.g. PAES, PASS) (Art. 116 of Directive No 2001/83/EC) Commercial reasons (excl. Art. 116, 117 of Directive No 2001/83/EC) Efficacy – Lack of efficacy (Art. 116, 117(1b) of Directive No 2001/83/EC) Particulars of Art. 8-11 incorrect/not amended as Art. 23 (obligation to keep dossier updated) (Art. 116 of Directive No 2001/83/EC)

Data columns	Format and allowed values
	Quality - Composition not as declared (Art. 116, 117(1d) of Directive No 2001/83/EC) Quality - Controls have not been carried out or MA obligations not fulfilled (Art. 117(1e) of Directive No 2001/83/EC) Risk/benefit - Not favourable (Art. 116, 117(1c) of Directive No 2001/83/EC) Safety - Medicine is harmful (Art. 116, 117(1a) of Directive No 2001/83/EC)
Does Cessation lead to Shortage	Yes No
Country	ISO code (2 digit) AT,BE,BG,HR,CY,CZ,DK,EE,EL,FI,FR,DE,,HU,IS,IE,IT,LV,LI,LT,LU,MT,NL, NO,PL,PT,RO,SK,SI,ES,SE,XI

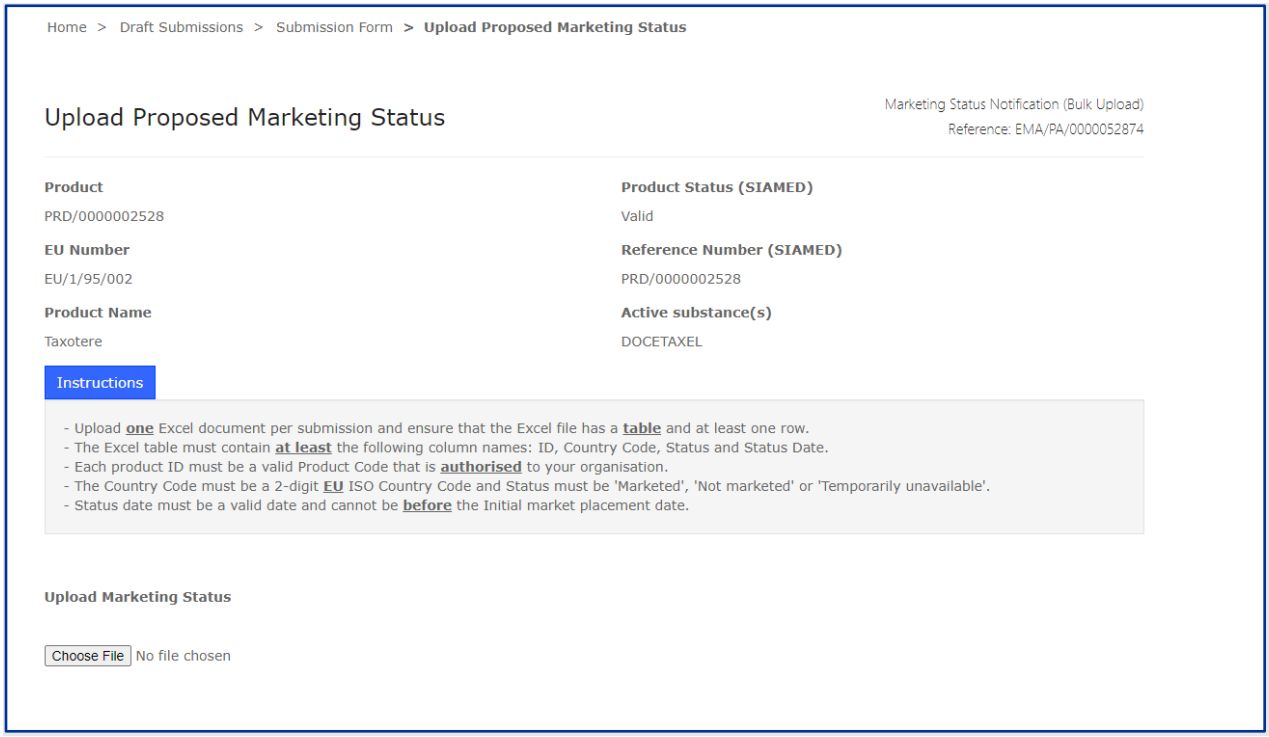
Figure 21. Download Excel



The **'Upload Proposed Marketing Status'** section is now enabled to upload the Excel file. Please do not use the Excel downloaded from the Marketing Status Report since it has a different format,

use only the Excel downloaded as explained in this section (above points). Click on the '**Notification'** button to read the instructions on uploading the file. Upload the file by clicking on the '**Choose file'** (Figure 22. Upload CSV file) button**.** Once the file is uploaded, click on **'Save and Return'.**

Figure 22. Upload CSV file



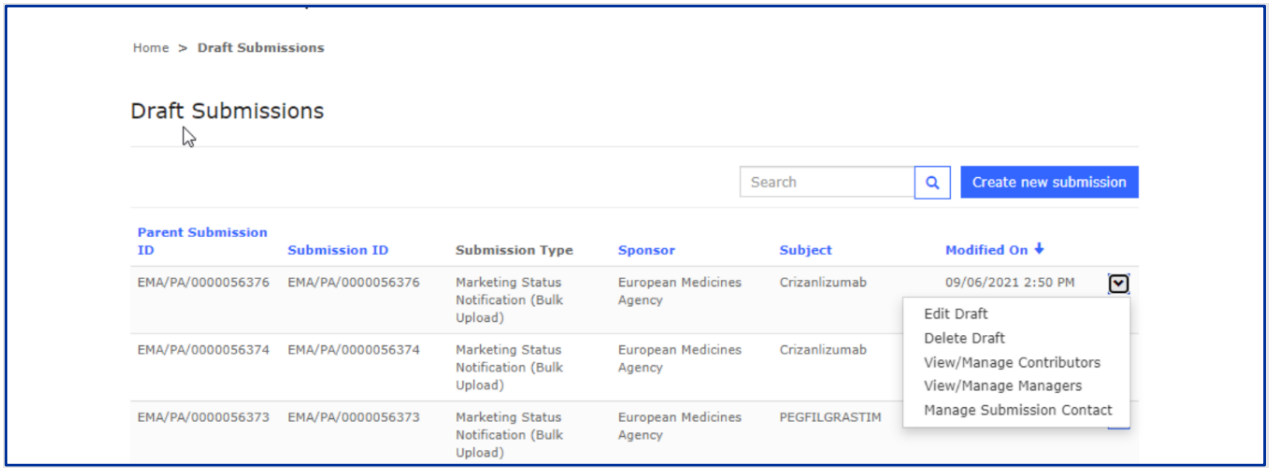
The **"View Proposed Marketing Status"** section will be blank at the time of submission. Data is added to the view once EMA has processed the case.

After completing the steps above, confirm the declaration and submit your application in the '**Submit Application'** section. You will receive a confirmation email on the successful submission.

Your submission is shown in the "**Submissions**/**Ongoing**" sub-tab.

You will receive an email if the system finds errors in the uploaded file. The submission will move back to the **"Draft Submissions"** section if errors are found. Please login to the IRIS portal, open the same submission by clicking on **'V'** shaped button in the right end corner of the record and selecting "edit draft".

Figure 23. Opening the submission in edit mode



Click on the **'Upload Proposed Marketing Status'** section (Figure 24. Excel Validation Errors). Errors will be shown under section **'Input File Validation'** as shown in Figure 25. Showing Validation errors and required corrections.

Figure 24. Excel Validation Errors

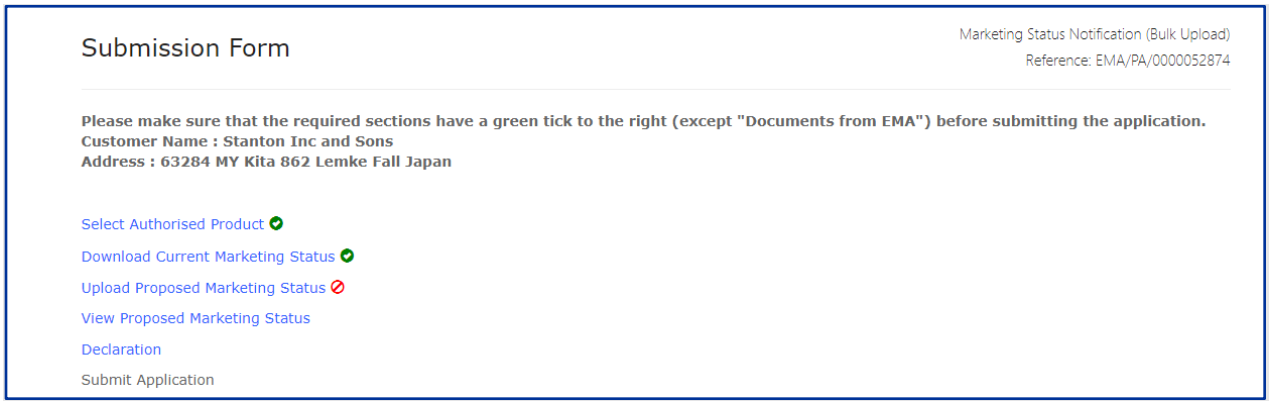
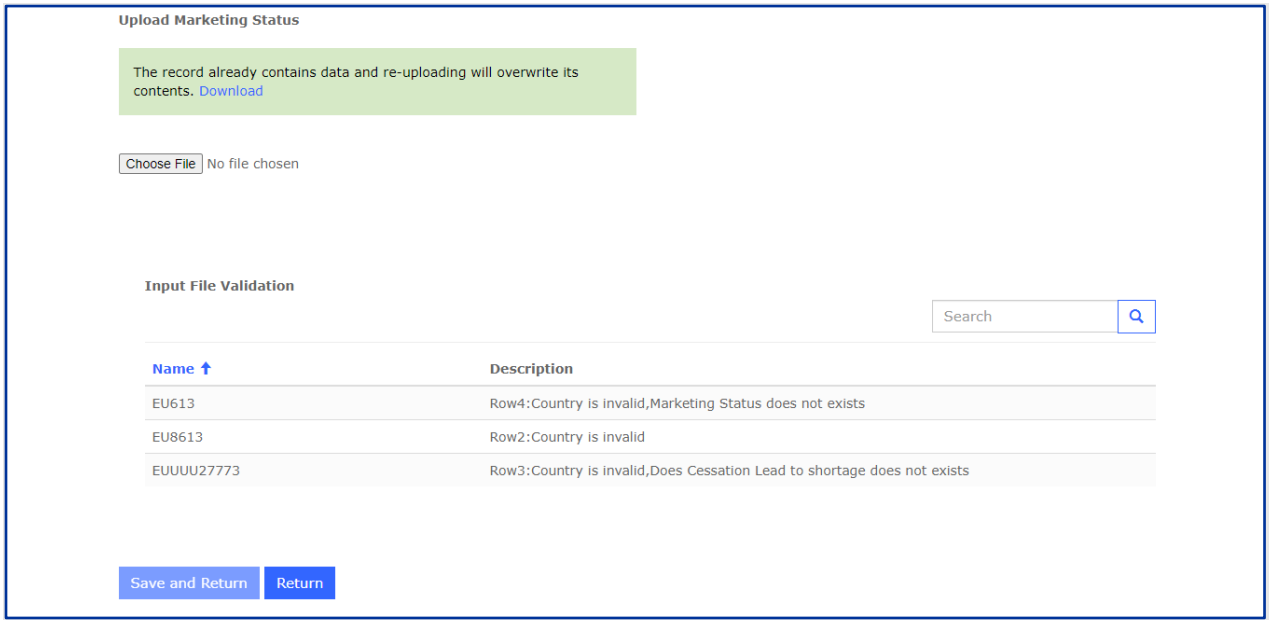


Figure 25. Showing Validation errors and required corrections



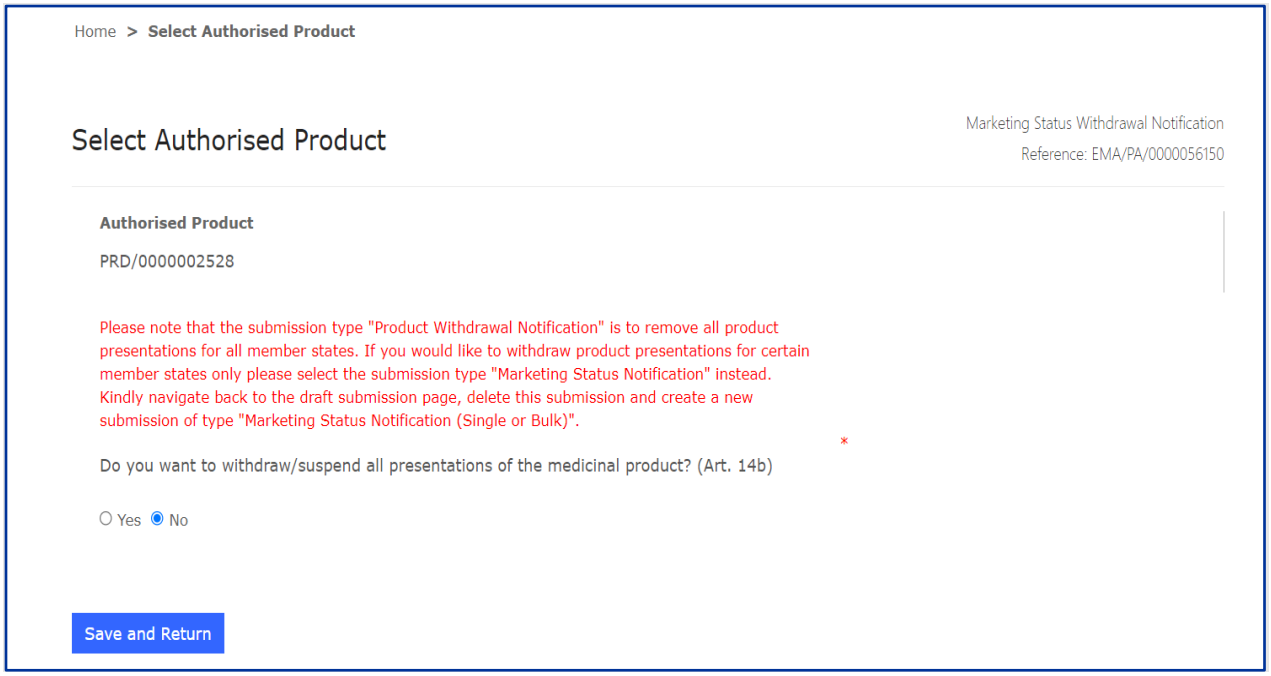
Download the file again by clicking on 'Download', correct the data and make a new submission.

6.3. Marketing status withdrawal notification

In addition to the steps in the general procedure as described in 2.3. **Create a new submission (general procedure for all submission types)**, select **"Marketing Status Withdrawal"** and note the following additional points:

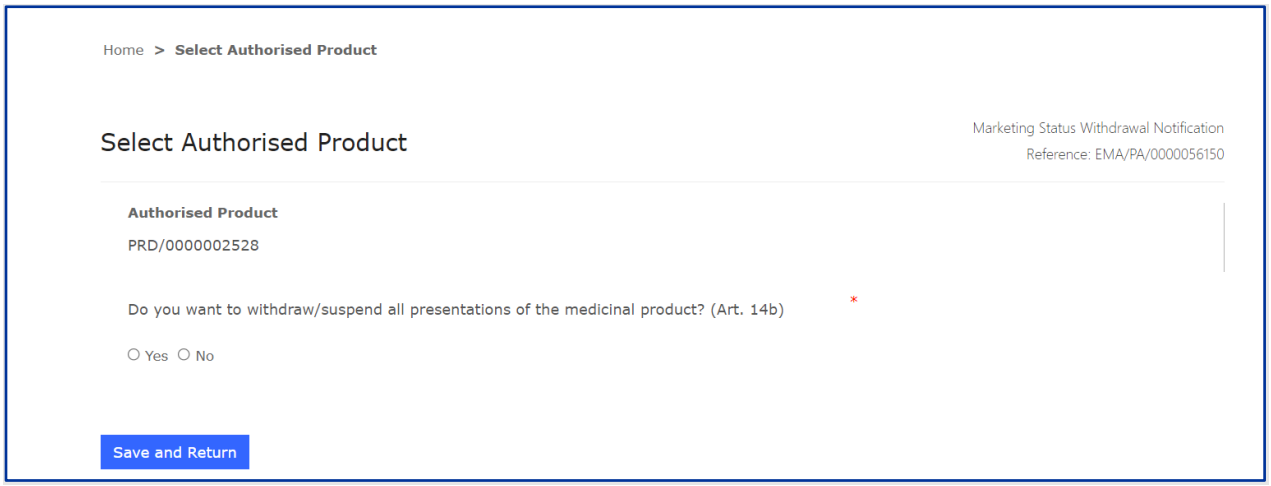
1. Select the Authorised product in section **"Select Authorised Product"**, click 'Next', and select one of the options to proceed further. Please note if you select **'No'** as option, then the system will provide a relevant message on proceeding further (Figure 26. Withdrawal of one or more presentations). You have to delete this draft submission yourself (2.7. Delete a draft submission);

Figure 26. Withdrawal of one or more presentations



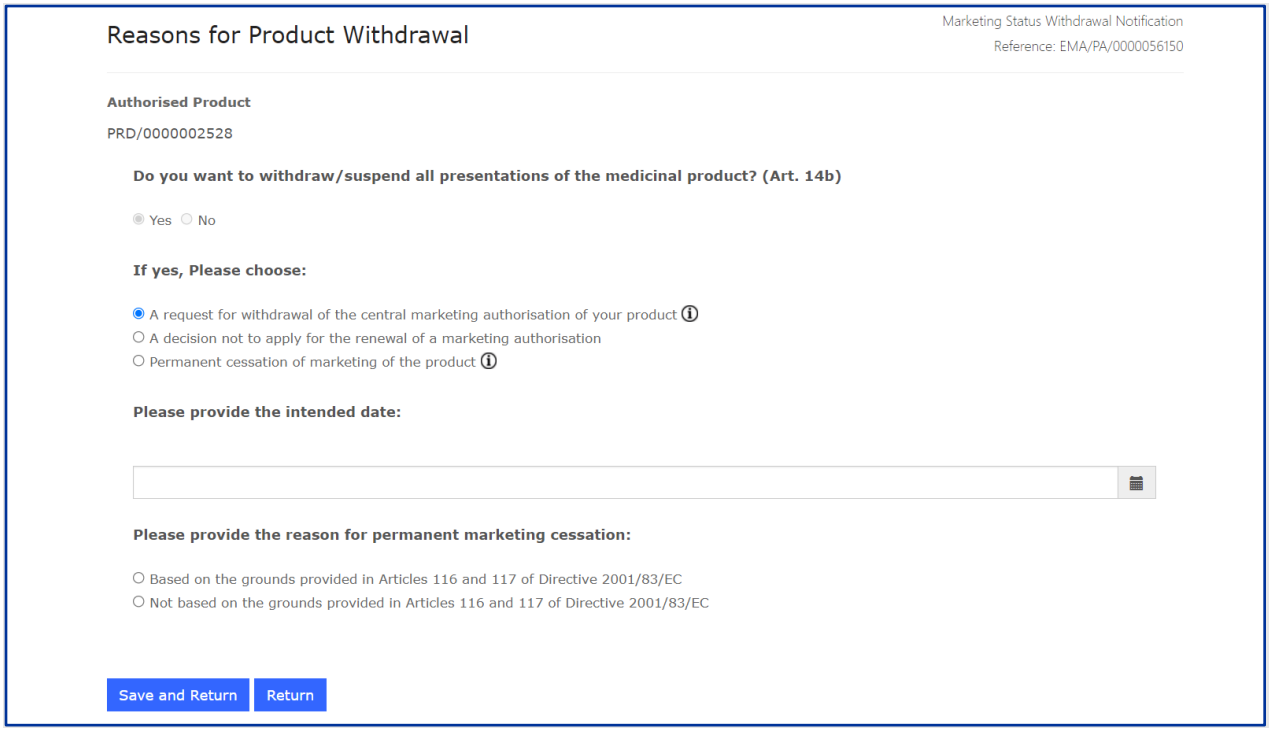
2. If you have selected '**Yes'**, the system will proceed to next step after clicking on 'Save and Return' button.

Figure 27. Withdrawal of all presentations



3. Click on the section **"Reasons for Product Withdrawal"** and choose one of the options as shown in Figure 28. Adding Reason for withdrawal and enter the details as requested based on the selection of data. Once you have entered the data in all the fields, click on 'Save and Return'.

Figure 28. Adding Reason for withdrawal



4. After completing the steps above, confirm the declaration and submit your application in the '**Submit Application'** section. You will receive a confirmation email on the successful submission.

Your submission is shown in the "**Submissions/Ongoing** "sub-tab. After the case (procedure) is completed by EMA, the submission will be moved to the "**Submissions/Completed'** tab. You will receive a confirmation email of the completion of the procedure.

6.4. Marketing status report

The Marketing Status Report can be accessed in IRIS Portal under the "**Products**" tab, Marketing Status Report. This report allows users[1] to see only the products they are entitled to visualise, i.e. those associated with an organisation to which they are affiliated to (for Industry users). Users will be able to filter and search the registry based on the data columns shown in Figure 29. Marketing Status Report. Searches can be made using a wildcard search (*/1/00/129/*) or selecting a value from the dropdown.

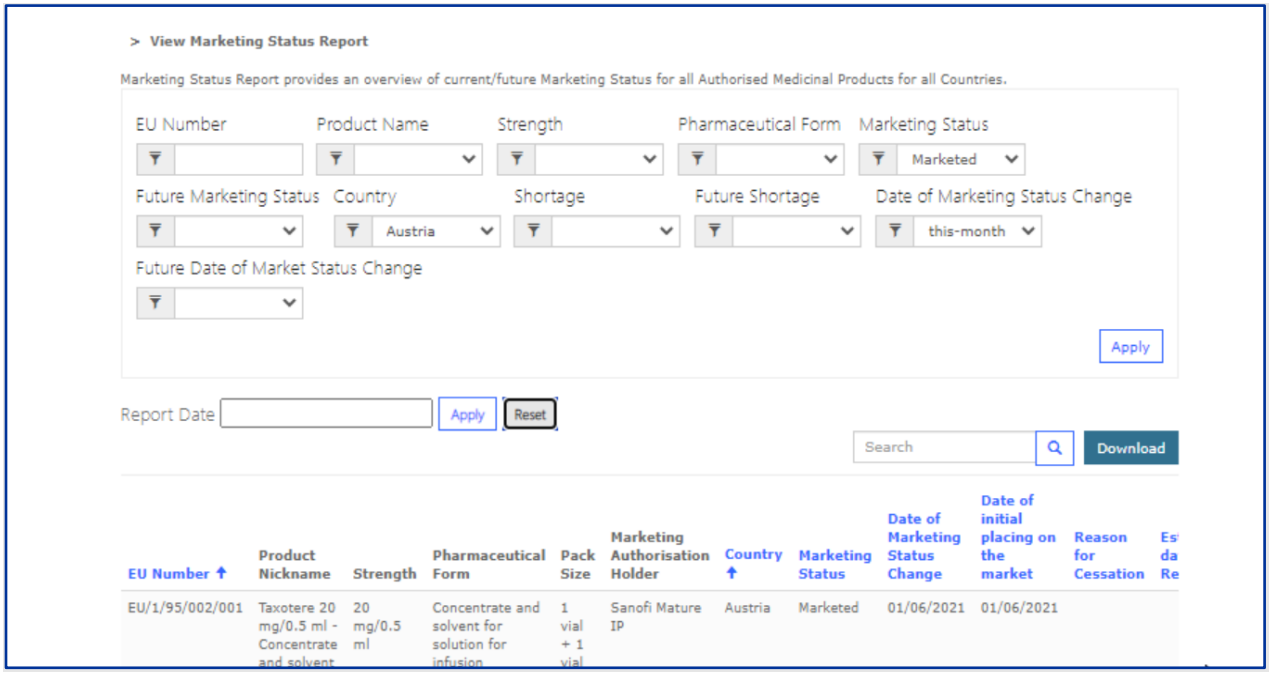
1. Once the search criteria have been selected, click on the '**Apply**' Button. The report is generated with all presentations as per the selected criteria.
2. Users can download the data shown in the table in an Excel file by clicking on the '**Download'** button. To reset and make new selections click on the '**Reset'** Button.

[1] Industry Portal users

3. Select the **'Report Date' in the future** to see the forecasted Marketing Status for all Authorised Products, all Presentations for all Countries on that selected date in the Marketing Status Report page. Please note that the ''**Download'** button will be disabled when this feature is on.

4. System allows to reset the report date to see Marketing Status for all Authorised Products, all Presentations for all Countries on current date.

Figure 29. Marketing Status Report



7. Inspections

7.1. GMP inspections

These inspections are requested by the Committee for Medicinal Products for Human Use and/or the Committee for Medicinal Products for Veterinary Use to verify compliance with Good Manufacturing Practice (GMP) of sites responsible for the manufacture of centrally authorised products.

The details of each of the inspections adopted by the Committee(s), including the contact details of the persons in the inspection services who will be involved can be found in the IRIS Industry portal: a new "submission" record is created for every organisation involved in an inspection case. Therefore, one inspection case may have multiple submissions with different reference numbers.

Of note, this is different from the normal IRIS behaviour, where an application is created by an applicant, and the EMA procedure(case) is created only at the time of submission.

Please let EMA know immediately, by replying to the email e-mail address from which the notification of the inspection request has been received, if any of the information given has changed or is incorrect. The inspectors may not always contact you as the MAH directly, instead they may liaise with the manufacturer to finalise the dates and detailed arrangements.

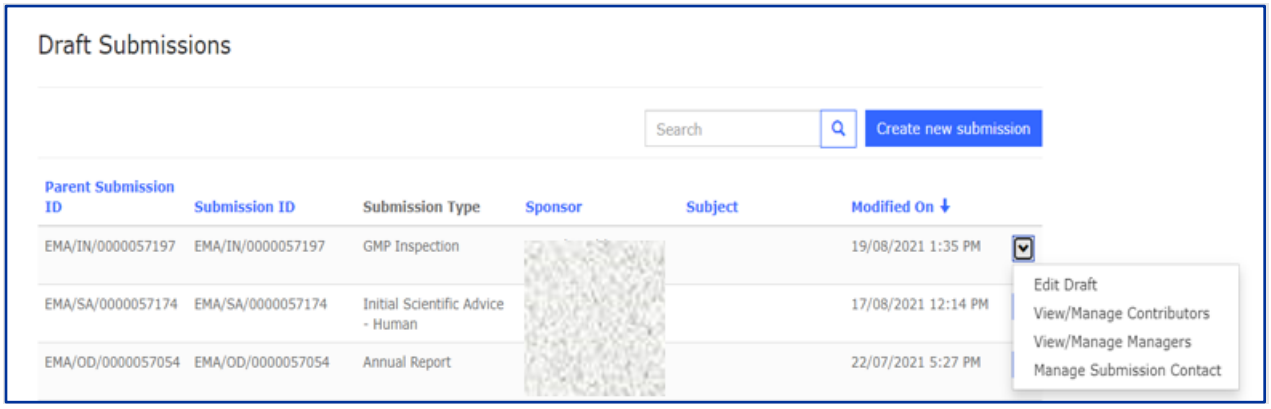
Upon adoption of a GMP inspection request by the CHMP or CVMP, the user[2] will receive a notification from EMA indicating that an inspection request has been adopted by the relevant committee (CHMP or CVMP) for one of their products. It is recommended that the e-mail address linked to the user is a personal e-mail address instead of a general e-mail address (e.g. john.doe@pharma.com instead of pharma.product@company.com).

At that point, you must update the submission with the necessary information (e.g. Purchase Order number) and submit it via the IRIS Portal. Please follow the steps below to submit the required information.

1. Login into IRIS Portal with EMA credentials and access '**My Draft Submissions'** present under '**Submissions'** tab;
2. You should have a Submission starting with **'EMA/IN/00000XXXXX'** and a submission type as '**GMP Inspection'.** Open the submission in edit mode by clicking on the 'V' icon present on the right-hand side of the screen as shown below (Figure 30. Edit Mode);

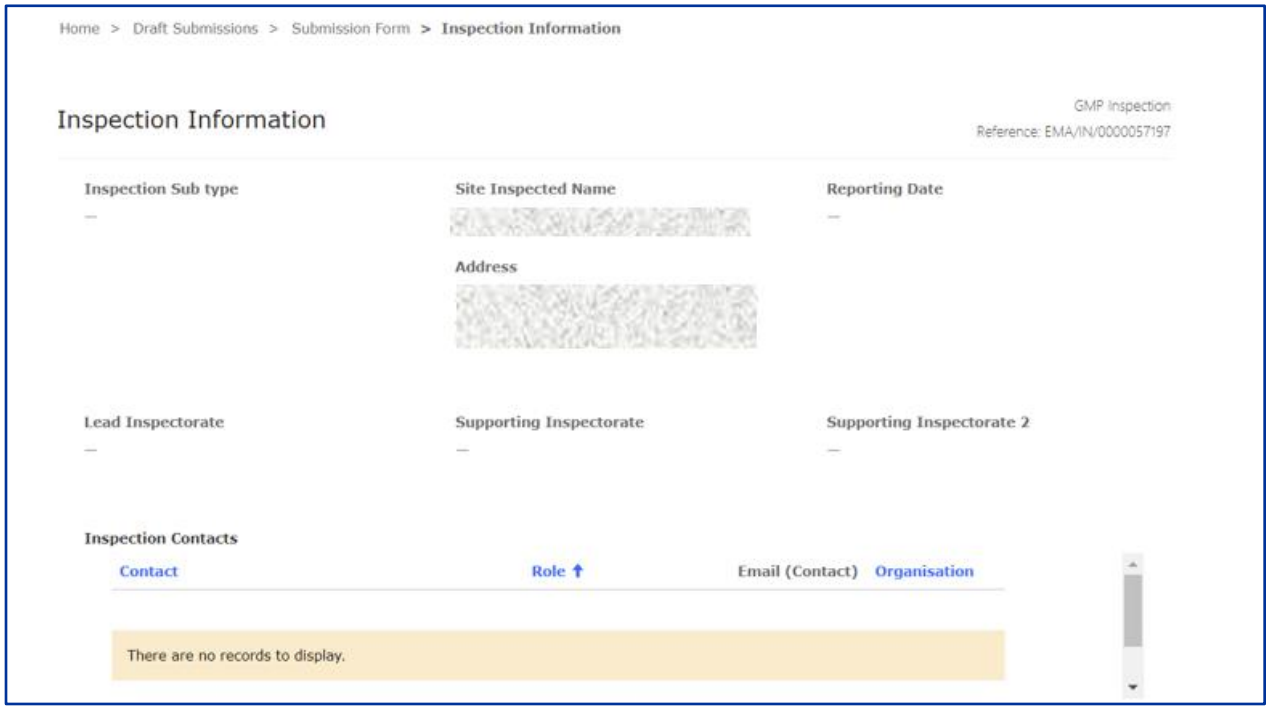
[2] The notified user is the existing Product Contact as already notified to EMA (integrated from SIAMED2); this user becomes the Portal Contact (a.k.a. Submission Contact) for the ongoing submission. To change the product contact, use the existing procedure.

Figure 30. Edit Mode



3. Click on the **'Inspection Overview'** section as shown in Figure 31. Inspection Information. Inspection related information will be shown: 'Inspection Sub Type', Site Name & address, Reporting date, Lead Inspectorate, Supporting Inspectorate and Contacts. click on '**Return'** to go back to the main menu;

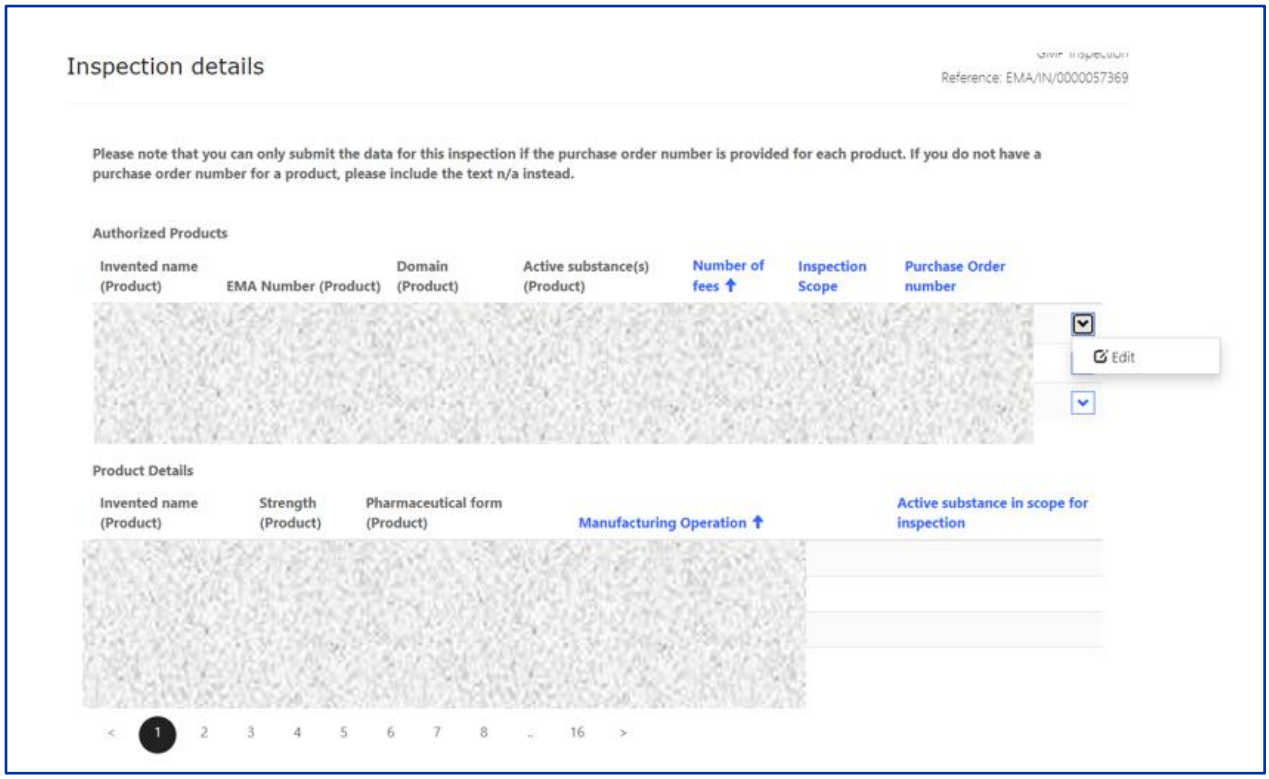
Figure 31. Inspection Information



4. Click on the **'Inspection Details'** section to view the information on Authorised Products.

Under the '**Authorised Products**' section, all authorised products are listed. You must add the Purchase Order Number (limited to 35 characters) for one of the products to submit the submission.

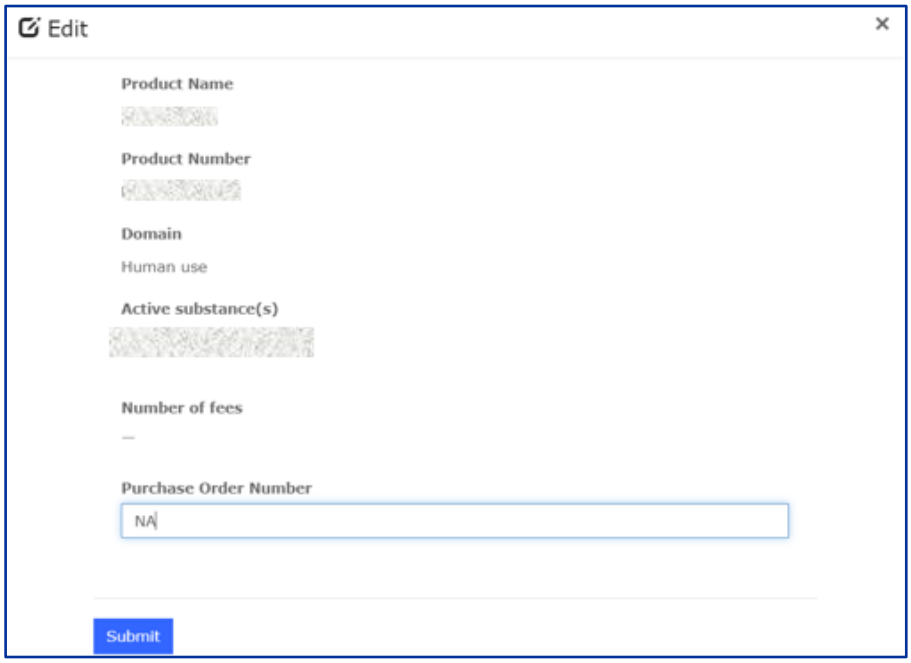
Figure 32. To Edit Purchase Order and fees



Click on edit as shown in Figure 32. To Edit Purchase Order and fees, enter the PO number. If you do not have a PO number, please add the text '**N/A'**, since this field is mandatory to proceed with the submission. Purchase order information will be quoted on the invoice issued for the inspection carried out. Please note that the EMA will not accept delays on payments based on missing purchase order (PO) reference number information. Once updated, click on the '**Submit**' Button and you will be taken back to the Inspection details screen. You can also add remarks under the section **'General Comments'**. If you have any questions related to the inspection case, please do not enter them in the general comments field but address them to the relevant EMA inspection co-ordinator by replying to the IRIS notification you received at the start of the process. When replying, please do not change the subject of the message to ensure the e-mail is correctly routed.

Click on '**Save and Return'** to save the details;

Figure 33. Adding Purchase Order Number



5. **Documents from Applicant**: this is a standard section of the submission form in IRIS, which is not used for co-ordination of GMP inspections, however it allows to add documents under this tab. Select the declaration confirming that documents have been attached and click on "Save and Return";

6. **Documents from EMA**: this is a standard section of the submission form in IRIS which is not used for co-ordination of GMP inspections and can be skipped as part of the drafting process (this tab is used to check if any documents have been made available by EMA);

7. **Declare and Submit changes**: Once all the above tabs have been filled and the green check marks show, the "**Declare and Submit changes**" button becomes enabled. Click on it and a new screen will open, select the checkbox asking for confirmation and click on the "**Submit Application"** button box. A pop-up window will appear, giving you a final opportunity to go back and check that all the details have been entered correctly ("**Review Application**"), or continue and submit. Once submitted, the submission will be shown in the "**Ongoing Submissions**" tab.

7.2. GCP inspections

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, and that clinical-trial data are credible.

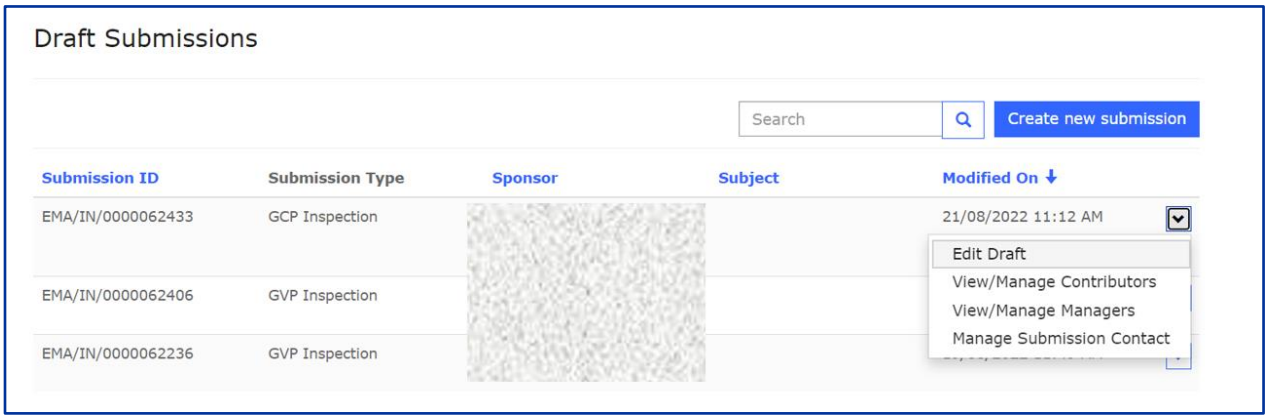
GCP inspections are adopted by the CHMP or CVMP and may be routine or may be triggered by issues arising during the assessment of the dossier. They are usually requested during the initial

review of a marketing authorisation application, but could also be requested post-authorisation following a regulatory submission.

Upon adoption of a GCP inspection, the user will receive an e-mail notification from EMA indicating that an inspection request has been adopted by the relevant committee (CHMP or CVMP) for one of their products. At that point, you must update the submission with the necessary information (i.e. Purchase Order number and requested documents) within 10 working days of the inspection announcement or otherwise agreed with the Reporting Inspector and submit it via the IRIS Portal. Please follow the steps below to submit the required information.

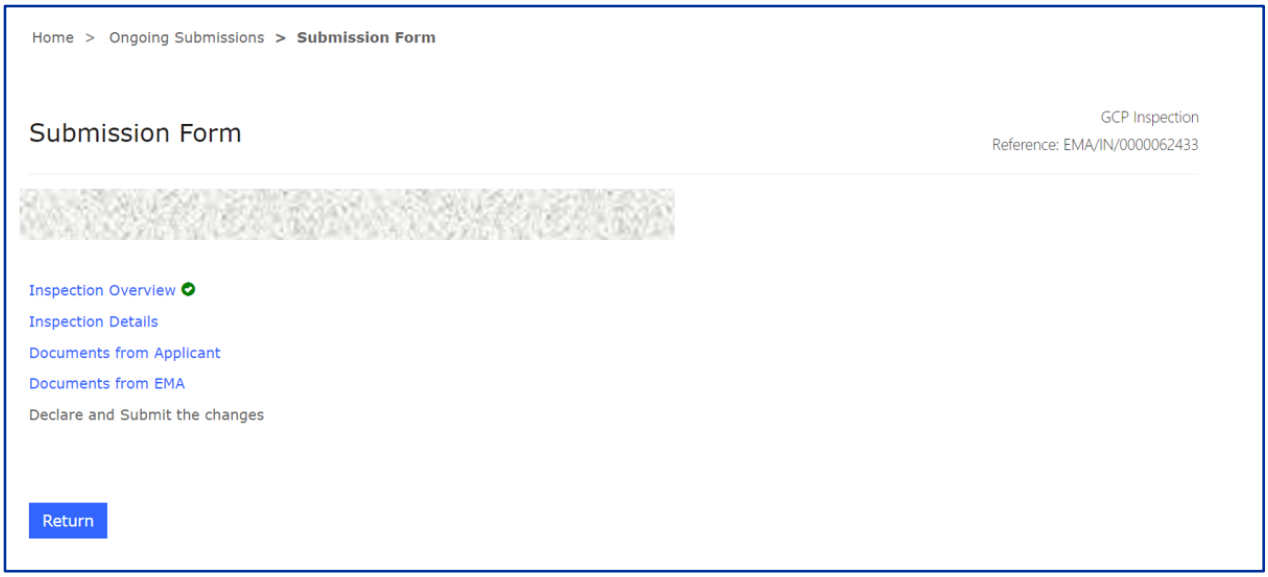
1. Login into IRIS Portal with EMA credentials and access '**My Draft Submissions'** present under '**Submissions'** tab.
2. You should have a Submission starting with **'EMA/IN/00000XXXXX'** and a submission type as '**GCP Inspection'.** Open the submission in edit mode by clicking on the '**V'** icon present on the right-hand side of the screen (Figure 34. Draft Submission).

Figure 34. Draft Submission



3. A submission form will open with the following sections: 'Inspection Overview', 'Inspection Details', 'Documents from Applicant', 'Documents from EMA' and 'Declare and Submit the changes' (Figure 35. Submission Form).

Figure 35. Submission Form

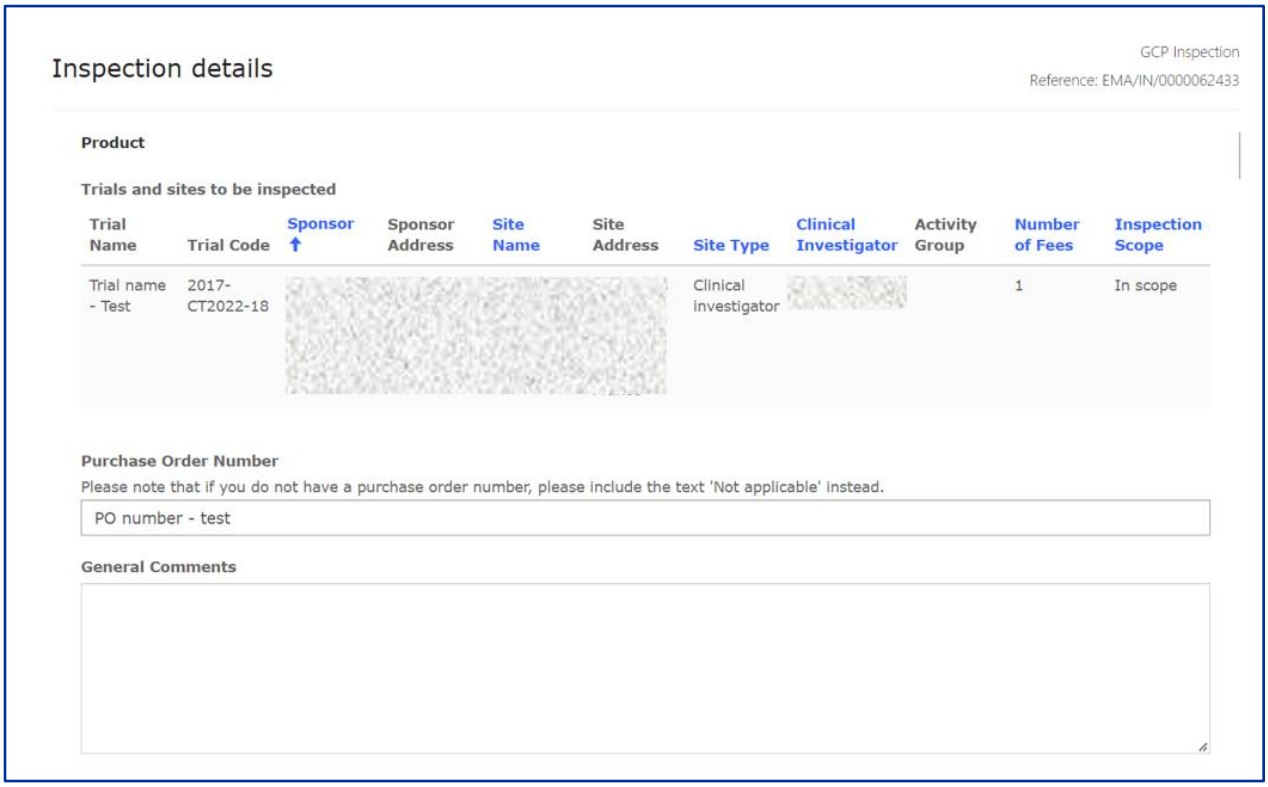


4. Click on the **'Inspection Overview'** section. Inspection related information will be shown: Product Name, Inspection Sub Type, Reporting deadline, Reporting Inspectorate, Supporting Inspectorates and Contacts. Click on '**Return'** to go back to the main menu.

5. Click on the **'Inspection Details'** section to view the information on trials and sites to be inspected. At the end of the page, you must add the Purchase Order Number (limited to 35 characters) in order to submit (Figure 36. Inspection details – pt.1).

If you do not have a PO number, please add the text '**N/A'**, since this field is mandatory to proceed with the submission. Purchase order information will be quoted on the invoice issued for the inspection carried out. Please note that the EMA will not accept delays on payments based on missing purchase order (PO) reference number information. You can also add remarks under the section **'General Comments'**. If you have any questions related to the inspection case, please enter them in the general comments field or address them to the relevant EMA inspection co-ordinator by replying to the IRIS notification you received at the start of the process. When replying, please do not change the subject of the message to ensure the e-mail is correctly routed. Once updated, click on the 'Save and return' Button and you will be taken back to the Inspection details screen.

Figure 36. Inspection details – pt.1



6. **Documents from Applicant**: It is possible to add documents under this tab. Select the declaration confirming that documents have been attached and click on "Save and Return".

7. **Documents from EMA**: This tab is used to check if any documents have been made available by EMA (e.g. the Integrated Inspection Report at the end of the process (if applicable)).

8. **Declare and Submit changes**: Once all the above tabs have been filled and the green check marks show, the "**Declare and Submit changes**" button becomes enabled. Click on it and a new screen will open, select the checkbox asking for confirmation that you have read this guidance and the 'Guidance for applicants/MAHs involved in GMP and GCP inspections co-ordinated by EMA' and click on the "**Submit Application"** button box. A pop-up window will appear, giving you a final opportunity to go back and check that all the details have been entered correctly ("**Review Application**"), or continue and submit. Once submitted, the submission will be shown in the "**Ongoing Submissions**" tab.

7.3. GVP inspections

GVP inspections are conducted to ensure that requirements for monitoring the safety of medicines are met. The responsibility for carrying out the inspections rests with the national competent authorities. EMA is co-ordinating GVP inspections requested by the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use.

Upon adoption of a GVP inspection, the QPPV for the pharmacovigilance system subject to the inspection will receive an e-mail notification from EMA indicating that an inspection request has

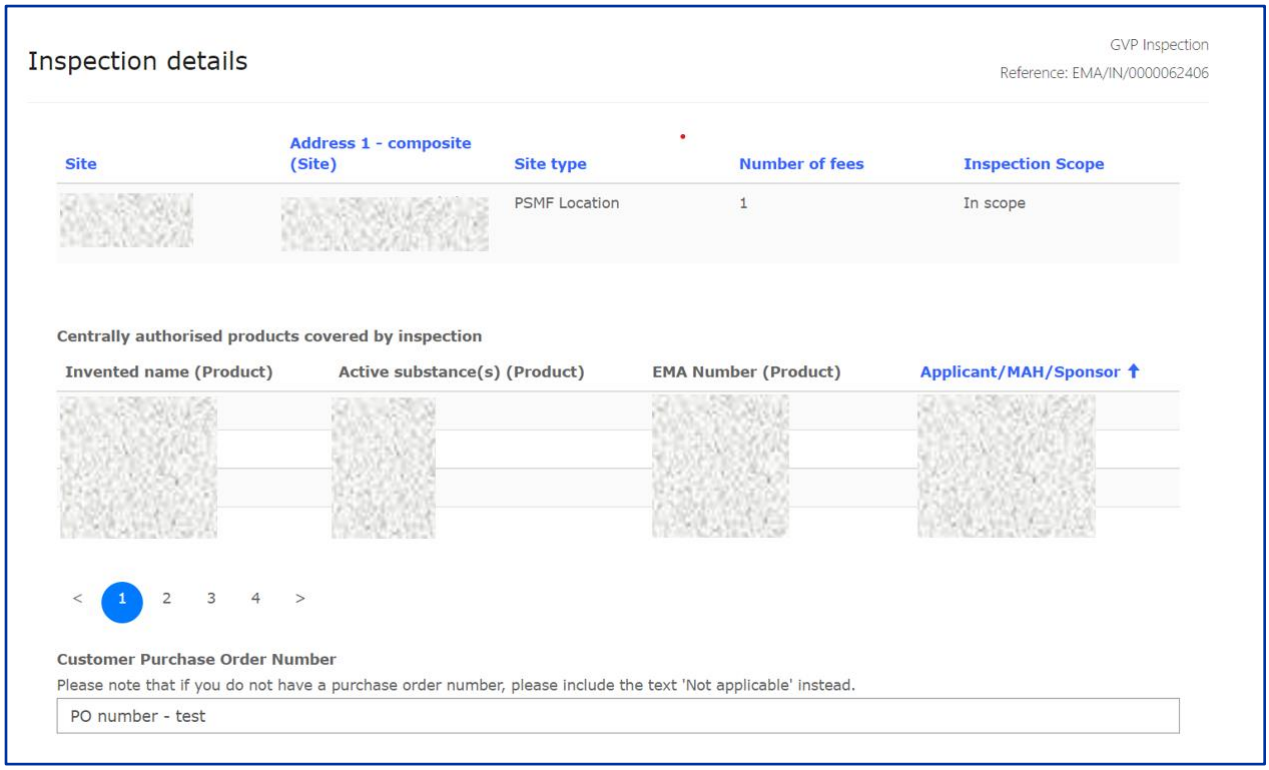
been adopted by the relevant committee (CHMP or CVMP). Details of an inspection can be viewed by logging into the IRIS portal. At that point, you must update the submission with the necessary information (i.e. Purchase Order number and requested documents) within 10 working days of the inspection announcement or otherwise agreed with the Reporting Inspector and submit it via the IRIS Portal.

Please follow the steps below to submit the required information:

1. Login into IRIS Portal with EMA credentials and access '**My Draft Submissions'** present under **'Submissions'** tab.
2. You should have a Submission starting with **'EMA/IN/00000XXXXX'** and a submission type as '**GVP Inspection'.** Open the submission in edit mode by clicking on the **'V'** icon present on the right-hand side of the screen (Figure 23. Opening the submission in edit mode).
3. Click on the **'Inspection Overview'** section. Inspection related information will be shown: PSMF Code, Inspection Sub Type, Reporting deadline, Reporting Inspectorate, Supporting Inspectorates and Contacts. Click on '**Return'** to go back to the main menu.
4. Click on the **'Inspection Details'** (Figure 37. Inspection details – pt.2) section to view the information on the sites to be inspected and products covered by the inspections. At the end of the page, you must add the Purchase Order Number in order to submit.

If you do not have a PO number, please add the text '**N/A'**, since this field is mandatory to proceed with the submission. Purchase order information will be quoted on the invoice issued for the inspection carried out. Please note that the EMA will not accept delays on payments based on missing purchase order (PO) reference number information. Once updated, click on the 'Save and return' Button and you will be taken back to the Inspection details screen.

Figure 37. Inspection details – pt.2



5. **Documents from Applicant**: It is possible to add documents under this tab. Select the declaration confirming that documents have been attached and click on “Save and Return”.

6. **Documents from EMA**: This tab is used to check if any documents have been made available by EMA (e.g. the Integrated Inspection Report at the end of the process (if applicable).

7. **Declare and Submit changes**: Once all the above tabs have been filled and the green check marks show, the “**Declare and Submit changes**” button becomes enabled. Click on it and a new screen will open, select the checkbox asking for confirmation that you have read this guidance and the ‘Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections co-ordinated by EMA’ and click on the “**Submit Application”** button box. A pop-up window will appear, giving you a final opportunity to go back and check that all the details have been entered correctly (“**Review Application**”), or continue and submit. Once submitted, the submission will be shown in the “**Ongoing Submissions**” tab.

8. Veterinary signal management

For specific information on veterinary signal management please consult the document "Guideline on veterinary good pharmacovigilance practices VGVP) Module: Signal Management" on the Pharmacovigilance (veterinary medicines) page of the EMA website and the tutorial documents on the "Union Pharmacovigilance Database: webinar on signal detection and analysis" page of the EMA website.

8.1. Annual statements submission

In addition to the steps in the general procedure as described in Section 2.3. "Create a new submission (general procedure for all submission types, except PLM procedures)", select "Annual statements submission" as the submission type. Note the following additional points as shown below (Figure 38. Submission Form):

Figure 38. Submission Form

1. The reference number will contain VS (e.g. EMA/VS/0000001234) for the draft submission.
2. Click on "**Select Authorised Products**" and then click on "**Add Products**", select the relevant product(s) (grouping of products will be allowed on the basis of same or similar products), click on "**Add**" and once the product(s) is(are) added, click on "**Save and Return**";
3. Click on "**Submission Details**", select the "**Period of analysis**" (i.e. "Date From" and "Date To") and select the relevant statement on the tab "**Benefit-risk balance**" (i.e. "I confirm that the benefit-risk balance remains unchanged" or "A procedure is ongoing concerning a new risk identified or a change to the benefit-risk profile"). The "Submission Details" step is completed once you click on the tick box next to the statement (that begins with the words: "I confirm...") and then click on "**Save and Return**";
4. Click on "**Documents from Applicant**" and add all corresponding documents (if applicable) by clicking on "**Add files**". For each uploaded document select the appropriate Document type (i.e. "Literature data" or "Other relevant risks identified" or "Other information"). Click on "**Save and Return**";

5. “**Documents from EMA**": This tab can be skipped initially, as part of the creation of a new submission process, as no documents are required from the applicant. It is used to check if any documents have been made available to you by EMA at a later stage;
6. Click on “**Declaration and Submission**”, 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 and then click on “**Submit Application**” to complete the submission of the annual statement.

8.2. Signal management submission

In addition to the steps in the general procedure as described in Section 2.3. “**Create a new submission (general procedure for all submissions type)**”, select “**Signal management submission**” as the submission type and note the following additional points:

1. Click on "**Select authorised products**” and then click on “**Add products**”. Select the relevant product(s), click on “**Add**” and then click on "**Save and return**”;
2. Click on “Submission details”;
    a. Fill in the **signal title** according to the following format:

“*Active substance – PRODUCT NAME = VeDDRA term (PT level) in species affected”* Please ensure the signal title is specific and does not concern general issues such as potential drug interactions or medication errors. In these cases, the consequences of the potential drug interaction or medication errors should be specified (e.g. “serious adverse drug reactions including bleeding events following potential drug interaction between X and Y").

a. Under “**Type of signal**”, select if it concerns a Signal or an Emerging safety issue (for which a 3-day notification requirement applies) or a Public announcement or a Submission of a regulatory measure.
b. Under “**Date of Analysis**”, select the date when the assessment was performed.
c. Click on “**Add Species**” and select the concerned animal species, then click “**Add**”.
d. Click on “**Add VeDDRA**”, select the concerned VeDDRA PT term(s) and then click on “**Add**”.
e. Under "**Previous signal submission**” you may link the current signal submission to any previous signal submissions in IRIS. E.g., if you previously submitted a signal concerning the same with the proposal to refute the signal, but with the current submission, the conclusion is to propose further regulatory actions such as an SPC update.
f. Under proposal for action, select the appropriate regulatory action(s).
g. Under “**Proposal for action description**”, please describe the specific proposals for regulatory action(s) indicated above in detail. For example: in case of amendment of the product information, you should provide here the specific wording to be amended or added to the SPC and the corresponding section(s) to be updated. In case of the signal being proposed to be refuted or for close monitoring, you should provide a brief summary

of the review of the cases, including the total number of cases, and the justification for the conclusion of the assessment.

h. Click on "Save and return".

3. Click on “**Documents from applicant**”. Then click on “**Add files**” and add the corresponding additional documents from the signal assessment. In case a thorough assessment is required, such as for signals with proposals for further regulatory action (30-day notification), please add here the filled template used for the signal assessment. Then click on “**Save and return**”;
4. Click on "**Declaration and submission**”, 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 and then click on “**Submit application**” to complete the signal management submission.

9. Registration of an MAH i-SPOC on supply and availability

Domain applicability: human

For general information on the legal requirements and objectives to register an Industry Single Point of Contact (i-SPOC), please consult Regulation (EU) 2022/123 article 9 and the Industry contact points for supply and availability of critical medicines section of the Availability of medicines page of the EMA website. For additional guidance on how to register an i-SPOC please see the demonstration video.

9.1. Purpose of this section

This section has been developed to show Marketing Authorisation Holders (MAHs) how to use the IRIS platform to establish and maintain an Industry Single Point of Contact (i-SPOC) on supply and availability issues for their portfolio of medicinal products (for human use) authorised in the Union.

The registration of an MAH i-SPOC takes place in a 2-step approach, as follows:

- **Step 1** - Set up of an EMA account and role. This prerequisite needs to be met to allow a successful registration in the IRIS portal. Further instructions are available within **Section 1.2 and 1.3**.
- **Step 2** – Create or maintain an MAH i-SPOC in the IRIS portal. Information on a successful creation or maintenance of an MAH i-SPOC is further detailed in **Section 9.2, 9.3, 9.4**.

9.2. Register an MAH i-SPOC

Who can register an i-SPOC?

In order to register or update the i-SPOC, user should have already an “IRIS Industry Manager” role in IRIS. Please be informed that only the user with an “IRIS Industry Manager” role in IAM/IRIS can successfully register or update an MAH i-SPOC within the IRIS portal

Who can be an i-SPOC?

The i-SPOCs should oversee the product supply chain, manufacturing capacity management and shortages.

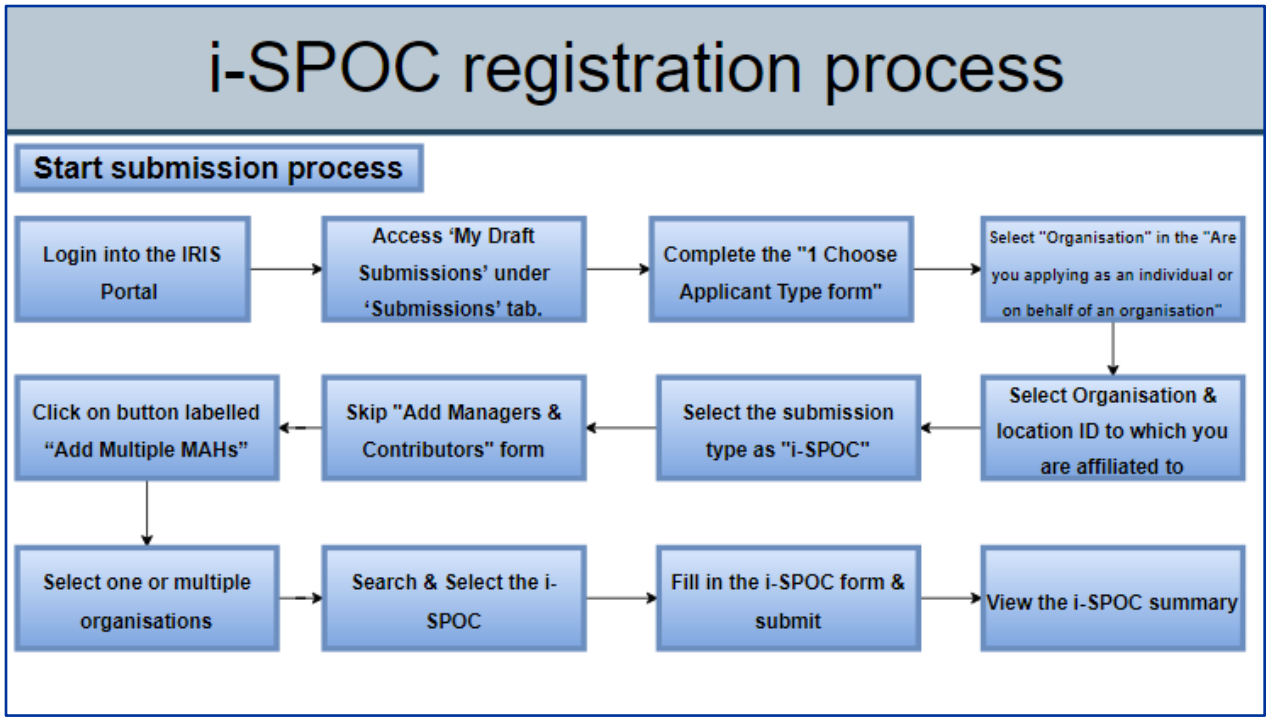
MAH staff registered as an i-SPOC must also be affiliated to the organisation in IAM/IRIS.

The nominated i-SPOC person can, nonetheless, be any MAH user with an “IRIS Industry Manager” or a “Contributor” role in IAM/IRIS.

Registration process in IRIS portal - workflow

The workflow and the detailed description below illustrate the various steps which need to be followed in order to complete a successful registration/maintenance of an MAH i-SPOC within IRIS portal end-to-end.

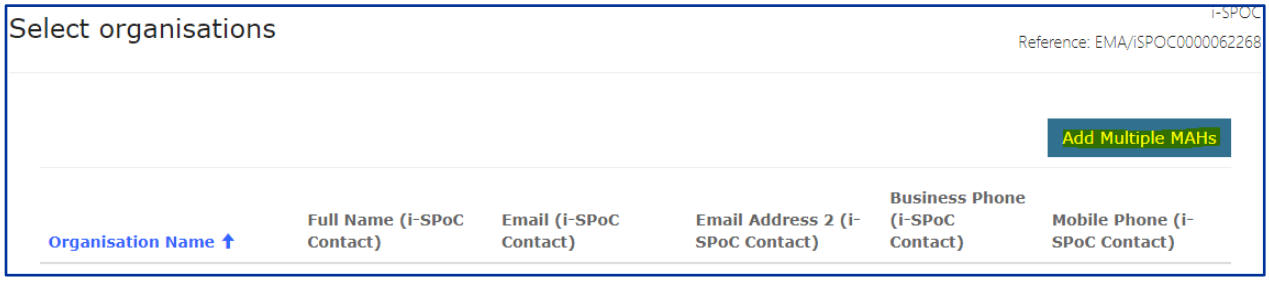
Figure 39. i-SPOC registration process



In addition to the steps in the general procedure as described in **Section 2.3.** "Create a new submission (general procedure for all submission types)", select "**Organisation**" in the "Are you applying as an individual or on behalf of an organisation" form and subsequently select "**i-SPOC**" as the submission type. Note the following additional points:

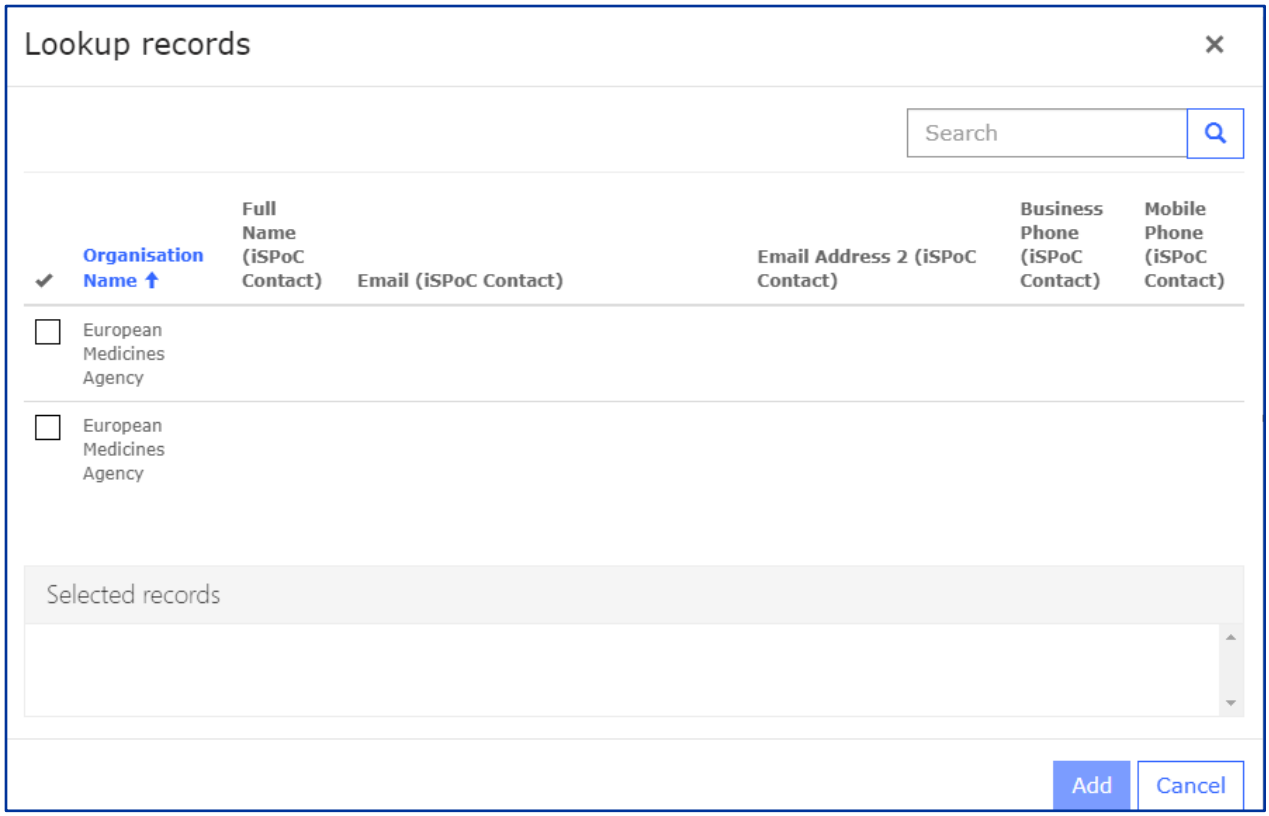
1. System will navigate the user to the next form named "Add Managers & Contributors". For i-SPOC registration, **no user action is required on this form** hence click on NEXT button & proceed to the next screen/form
2. In the next screen, click on button labelled "Add Multiple MAHs". System will display the list of your affiliated organisations

Figure 40. Select organisations



3. Select your organisation for which you want to register an i-SPOC. Post selection, click on "Add" button.

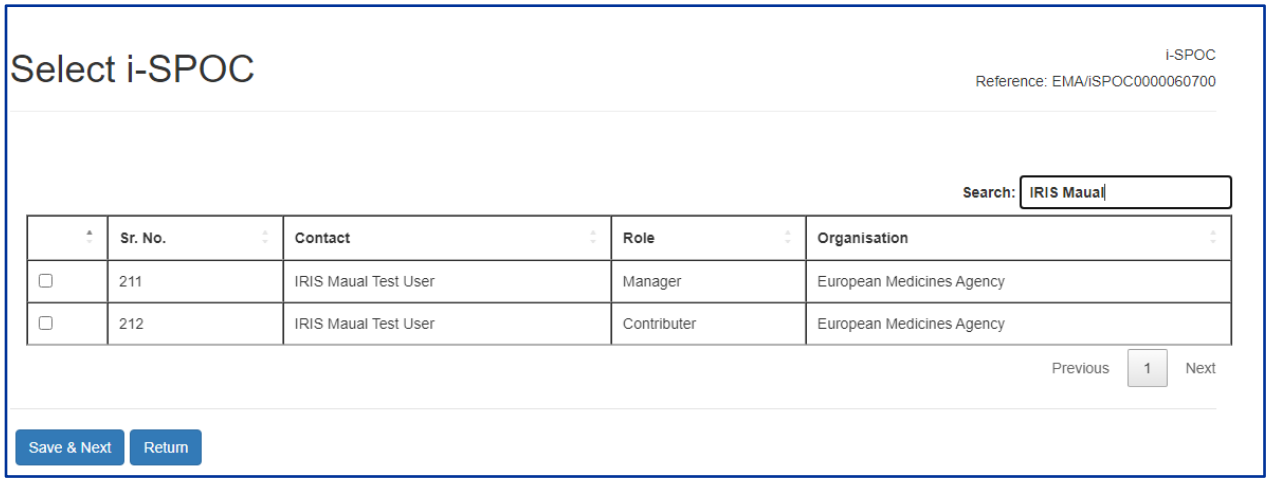
Figure 41. Lookup records



NOTE: Listing of organisations in this screen is **dependent on your affiliations in IAM**. The system will list all the organisations to which you are affiliated with a manager role.

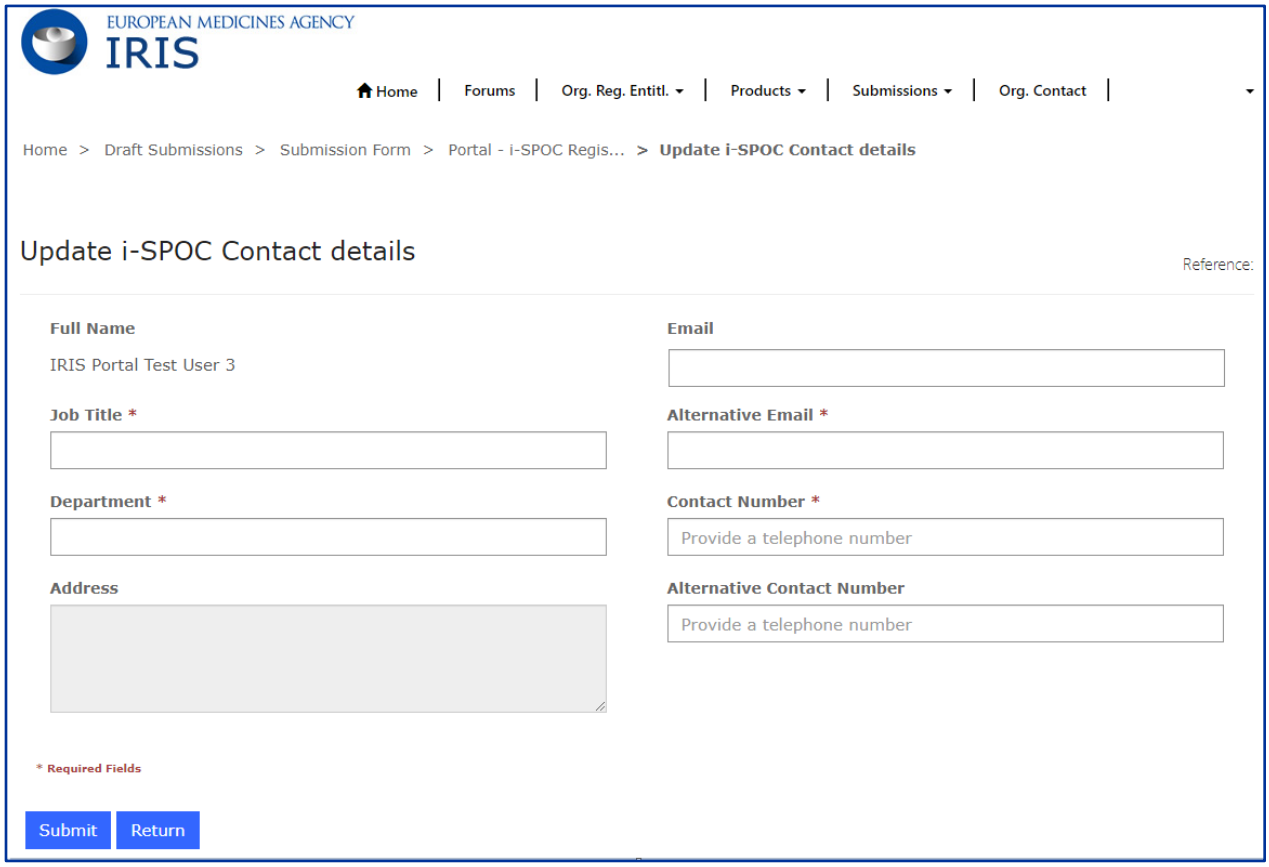
4. After the selection of the organisation, system will prompt you to select the i-SPOC. A list is presented/displayed with all affiliated users for selection. You can filter/search for i-SPOC user & select an individual record. Click on Save & Next button

Figure 42. Select i-SPOC



5. User is prompted to fill in the additional information about the contact details of the MAH i-SPOC. Fields "Job Title", "Department", "Alternative Email" are mandatory in nature. Simultaneously, ensure that “Alternative email” address is different than the i-SPOC email address. Either “contact number” or “Alternative contact number” information should be provided. System will prompt an error message if the mandatory information is not populated. Mandatory information is marked with an asterisk (*). Click on the Submit button;

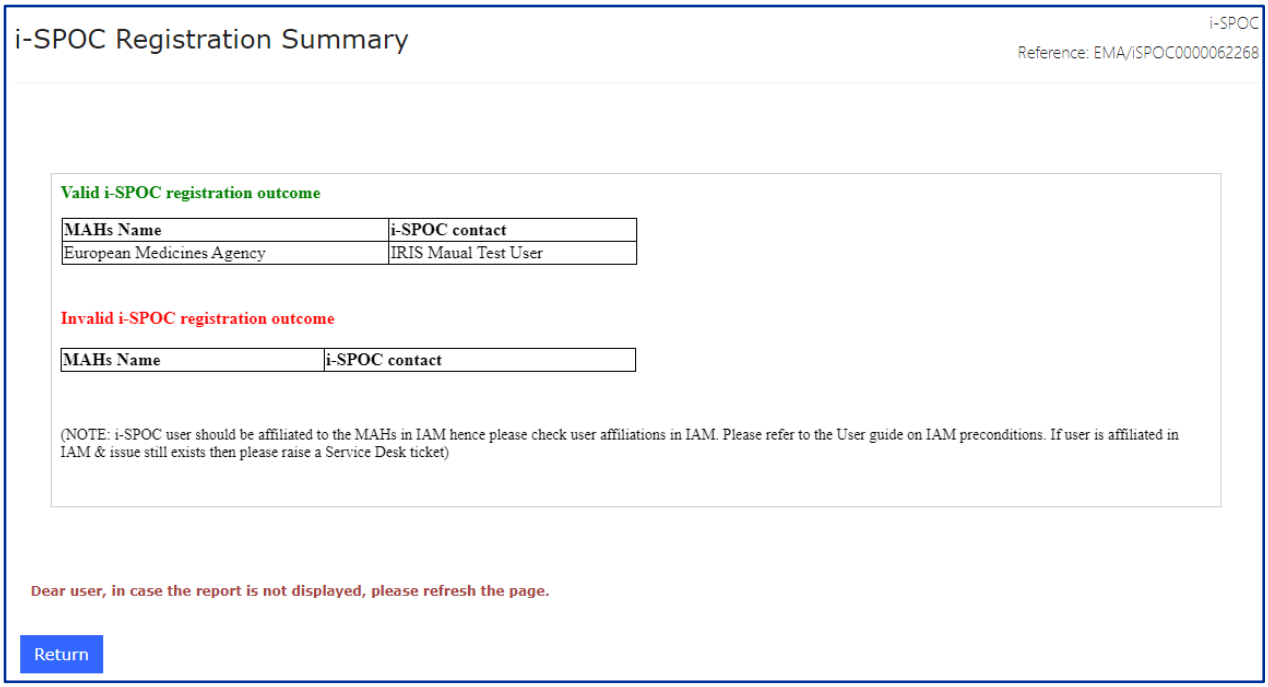
Figure 43. Update i-SPOC Contact details



6. System will notify you of the registration outcome (i.e., successful/unsuccessful) by displaying an outcome summary screen message.

    a. **Valid** registration outcome - i-SPOC user should be affiliated in IAM/IRIS with the organisation. During the registration process, if the user selects the i-SPOC who is affiliated to the selected organisation; then the registration will be successful & information will be displayed in the section under the green font header.

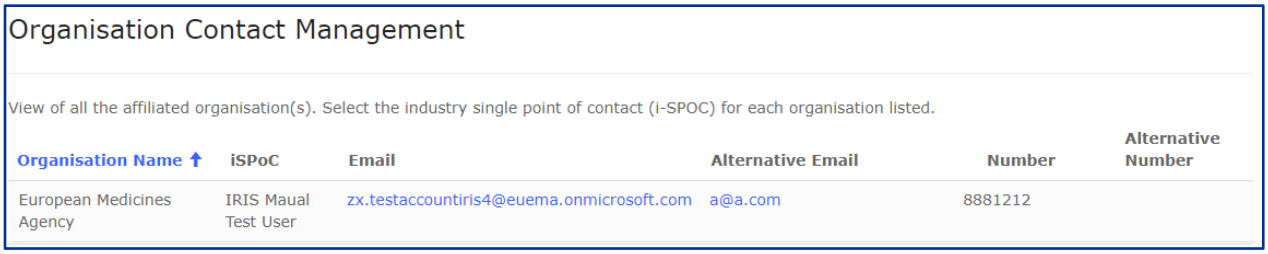
Figure 44. i-SPOC Registration Summary



b. **Invalid** registration outcome – When the user registers an i-SPOC for multiple organisations at once, then it my happen that selected i-SPOC is not affiliated to all the selected organisations. In such case, system will not register the i-SPOC & list the same in the section under the red font header.

7. Click on "Org. Contact" menu option to view the registered i-SPOC contact(s).

Figure 45. Organisation Contact Management



9.3. Update an MAH i-SPOC

For modification of an MAH i-SPOC, user will have to create a new submission & follow the general procedure as described in **Section 9.2**.

9.4. Maintain the same i-SPOC for multiple local affiliates

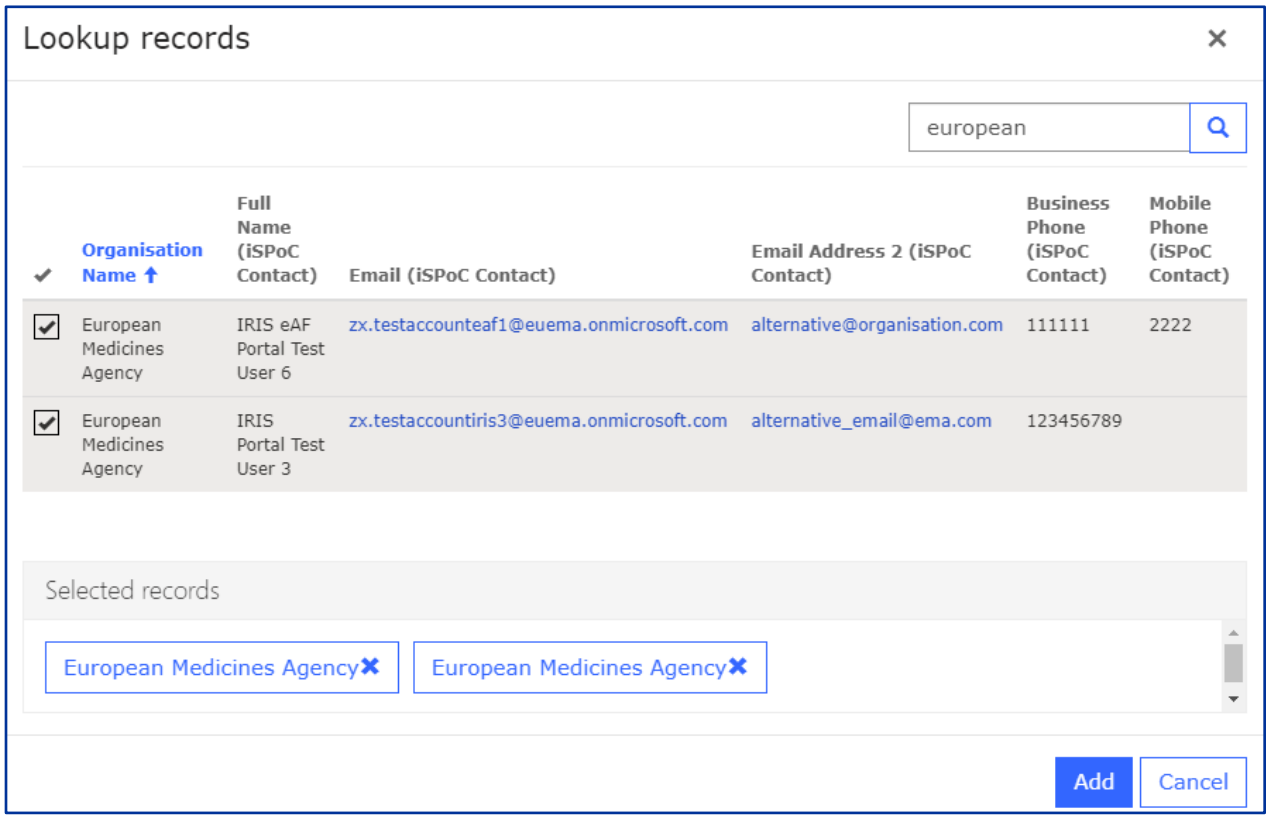
MAHs may wish to maintain their i-SPOC at company Headquarter level, instead of an i-SPOC at each individual company affiliate level. Hence, during the registration process the system will allow MAH users to create or maintain a single i-SPOC person for multiple, local affiliates (or organisations).

Please be aware that in order to have a MAH centralised at Headquarter level the MAH user must be affiliated in IAM/IRIS to multiple local organisations.

Please follow the standard steps of the i-SPOC registration described in **Section 9.2**. Note the following additional points:

1. In the "Select organisations" screen, click on button labelled "Add Multiple MAHs". System will allow the user to select multiple organisations to which they are affiliated to.

Figure 46. Lookup records



2. After the selection of the organisation(s), system will prompt you to select the i-SPOC. List displays all the affiliated users for the selected organisations. You can filter/search for i-SPOC user & select an individual record. Click on Save & Next button
3. Complete the remaining steps defined in Section 9.2.

10. PRIME eligibility

Domain applicability: human

For general information on PRIME Eligibility procedures, please consult the PRIME: Priority medicines section of the EMA website.

For specific information on how to submit an application for PRIME Eligibility, including the supporting documentation) please refer to the European Medicines Agency Guidance for applicants seeking access to PRIME on the EMA website.

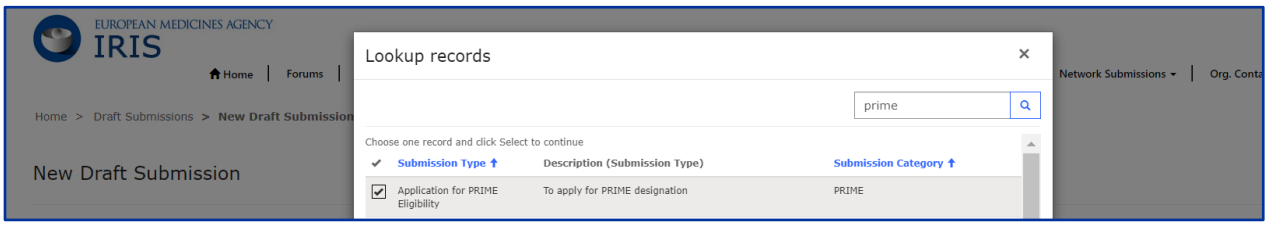
10.1. Create an application for PRIME eligibility

Step-by-step guidance on how to create a submission, please refer to the generic steps described in section 2.3.

For process specific step, please follow the steps below:

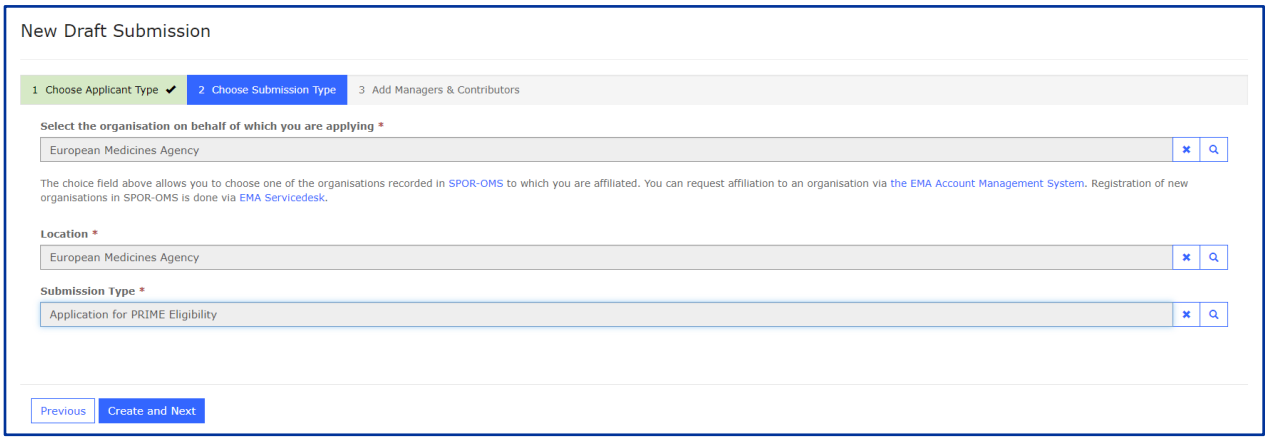
- When choosing the submission type, **"2. Choose Submission Type"** click on the magnifying glass symbol in the drop-down list and type in a keyword (e.g., PRIME) or the process type you wish to apply for (e.g. **Application for PRIME eligibility**).

Figure 47. Submission Form steps



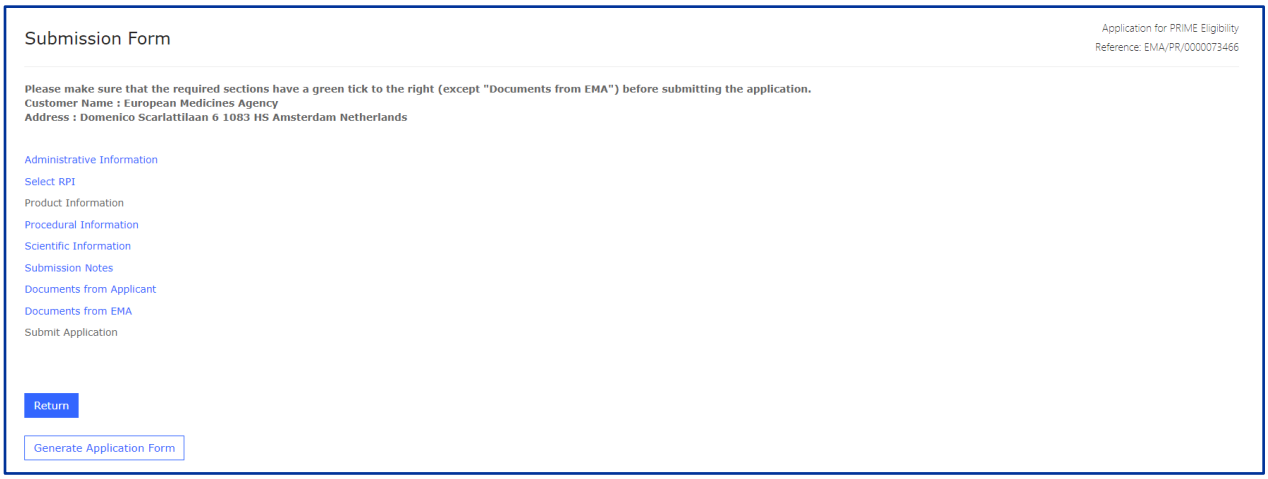
- Once all three fields in step 2 are selected click "Create and Next".

Figure 48. Submit Submission Type



- In the Submission form there is a list of nine steps (tabs) starting with "**Administrative Information**" and ending with "**Submit Application**" relating to the PRIME Eligibility Application displayed on the left-hand side of your screen.

Figure 49. Submission Form steps

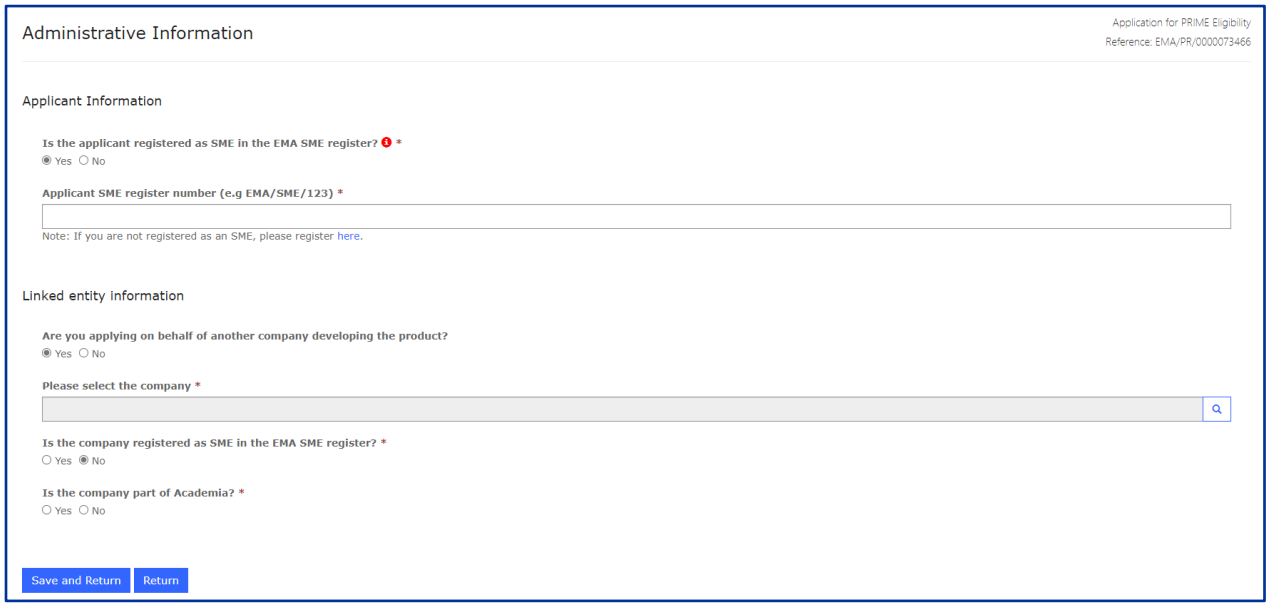


Note the following additional points:

- the reference number follows the format EMA/PR/0000001234, which is assigned automatically for your draft submission displayed on the upper right-hand side of the screen.
- the two sections "Administrative Information" and "Select RPI" must be completed, before the section (tab) "Product Information" becomes available (turns from grey to blue);
- the section (tab) "Submit Application" becomes available (turns from grey to blue) only when all mandatory sections, including "Documents from Applicant" are completed.
- all the mandatory field(s) marked with a red asterisk "*" should be completed.

- In section "**Administrative information**", you need to indicate the registered SME status or if you are part of Academia.
  - If the applicant is registered as SME, enter the "Applicant SME register number" (e.g., EMA/SME/123). If an SME applicant is not yet registered, please consult the "Applying for SME status" section of the EMA website.
  - If you are applying on behalf of another company developing the product, please select the relevant company in the "Linked entity information" section.

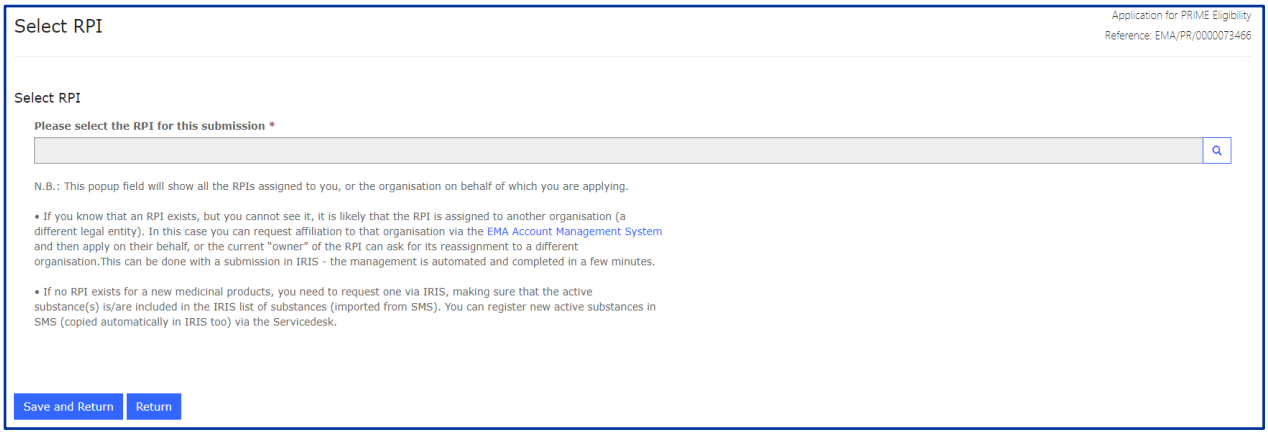
Figure 50. Administrative Information



Click "Save and Return".

- In section "**Select RPI**", please note that only RPIs "owned" by the applicant, or by the organisation on behalf of which he is applying, can be added.
  - Use the magnifying glass search symbol to look up and select the correct RPI.
  - If you know that an RPI exists, but it does not appear in the records, it is likely that the RPI is assigned to another organisation (a different legal entity). In this case you can request affiliation to that organisation via the EMA Account Management System and then apply on their behalf, or the current "owner" of the RPI can ask for its reassignment to a different organisation. This can be done with a submission in IRIS - the management is automated and completed in a few minutes.
  - If no RPI exists for a new medicinal product, you should request one via IRIS, making sure that the active substance(s) is/are included in the IRIS list of substances (imported from SMS). New active substances can be registered in SMS (and registered automatically also in IRIS) via the ServiceDesk.

Figure 51. Select RPI



- In section "**Product Information**" the system displays relevant information on the selected RPI, such as product name, type of product and mechanism of action. Additionally, can provide other information which you find relevant of the submission about this product.

Figure 52. Product Information

- In this section the system also displays **submission pipeline information** that is recorded on PRI "Information on Submission Pipeline". Please check this information and, if needed, update in the "Update Information on Submission Pipeline" section and provide explanation for the proposed change in the free text box. Please note that any changes made in these fields will result in updating also the information of the RPI record.

Figure 53. Information on Submission Pipeline

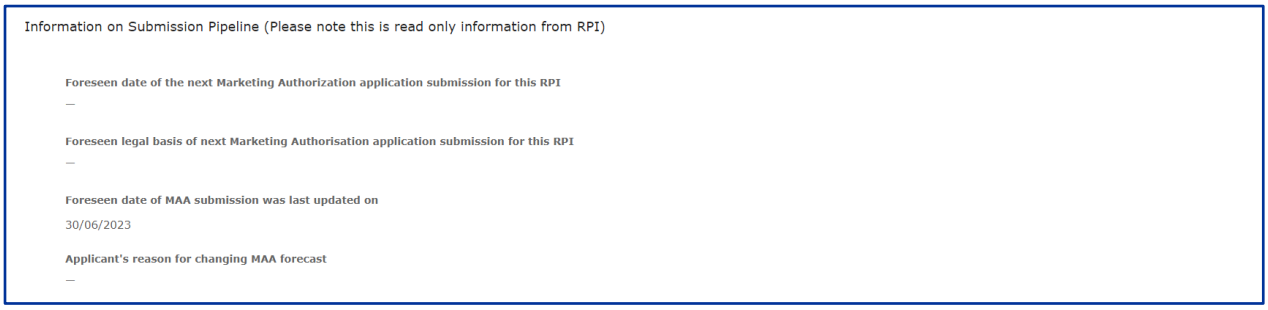
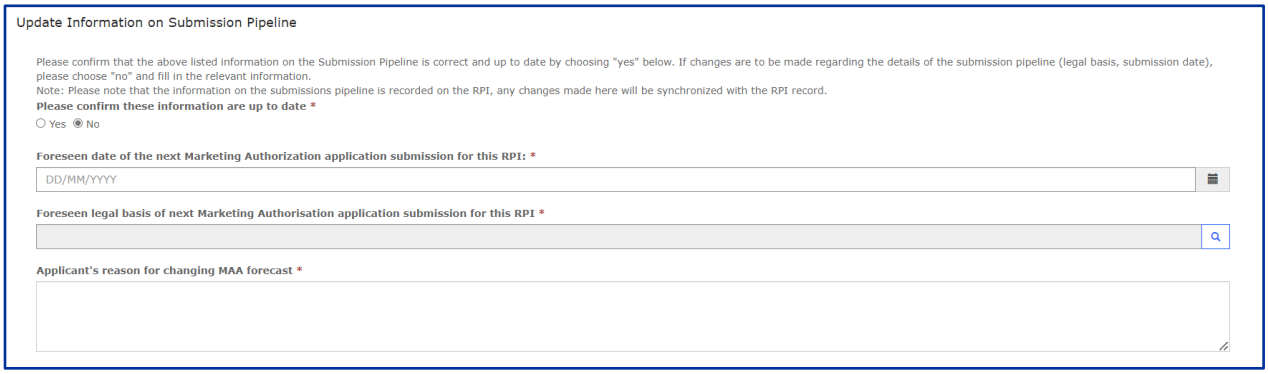
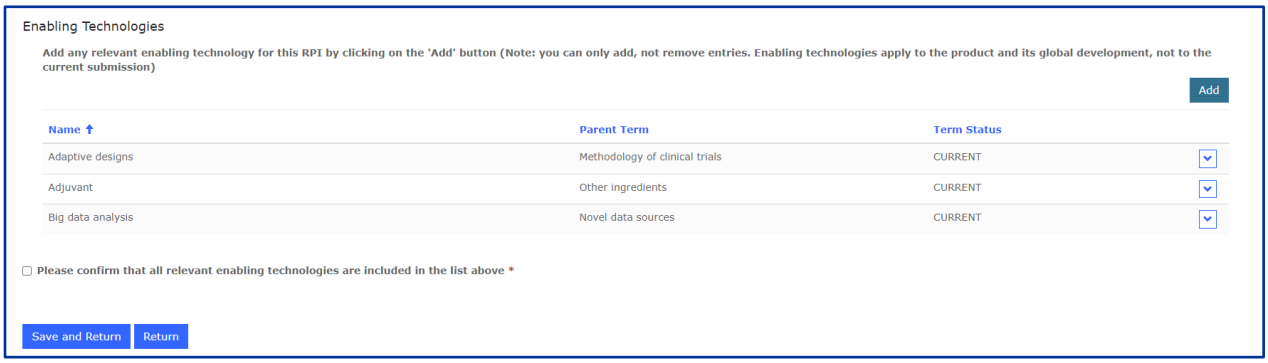


Figure 54. Update Information on Submission Pipeline



- Add any relevant "Enabling technology" for this RPI by clicking on the "Add" button. Enabling technologies apply to the product and its global development, not to the current submission. Please confirm that all relevant enabling technologies are included in the list by ticking the box.

Figure 55. Enabling Technologies



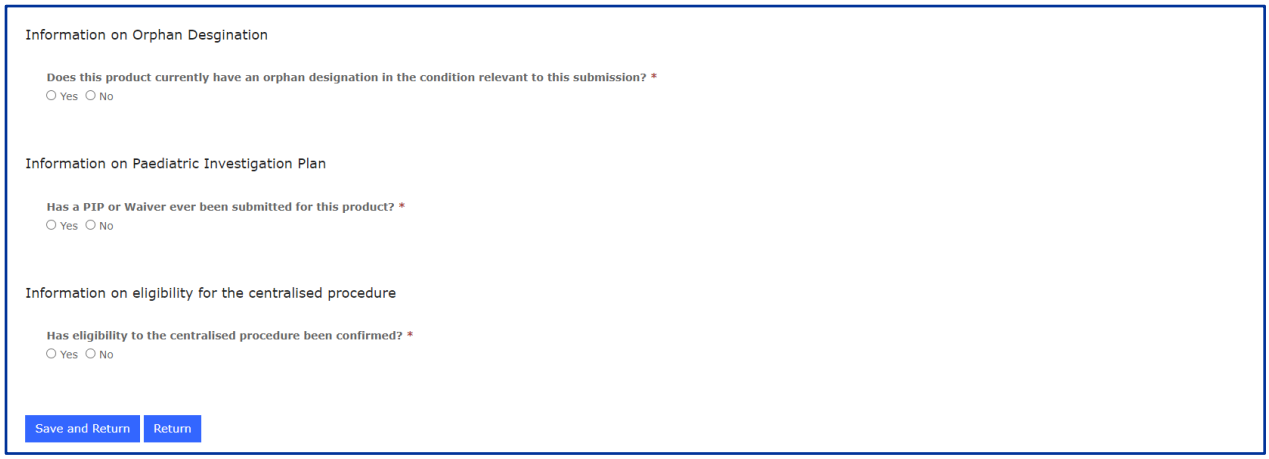
- In section "**Procedural Information**", please complete all mandatory fields.
  - If the product currently holds an "Early-Entry PRIME designation", please choose the PRIME designation number using the magnifying glass search symbol.

- If the current application is a "resubmission of a previously denied/withdrawn PRIME eligibility request", please choose the previous PRIME eligibility submission number.
- If a PRIME eligibility "pre-submission meeting" was held prior to the current submission, please enter the Pre-submission meeting date.
- If "National Scientific Advice" has been provided in the past, please add the relevant information by clicking on the "Add" button.

Figure 56. Procedural Information

- If the product holds an "Orphan Designation" in the condition relevant to this submission, please choose the Orphan Designation Number.
- If a "PIP or Waiver" has been submitted for this product, please enter the PIP/Waiver procedure number (e.g. EMEA-xxxxxx-PIPxx-xx). If a PIP or Waiver has not been submitted, please enter the date of planned PIP submission.
- If eligibility to the "centralised procedure" been confirmed for this product, please enter the corresponding Product Number (H000xxxx).

Figure 57. Procedural information

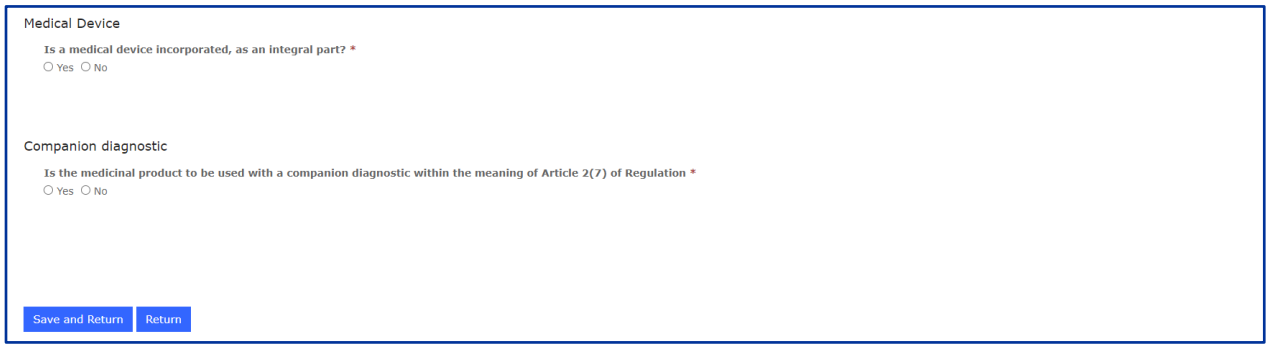


- In section "**Scientific information**", please complete information on the condition to be treated by entering the "Proposed scope" (Treatment, Diagnosis or Prevention), the "Proposed Condition/Indication" and select all types of "data supporting the PRIME application".

Figure 58. Scientific information

- Notes relating to medical devices and companion diagnostics should also be answered in this section.

Figure 59. Information on Medical Device and Companion diagnostics

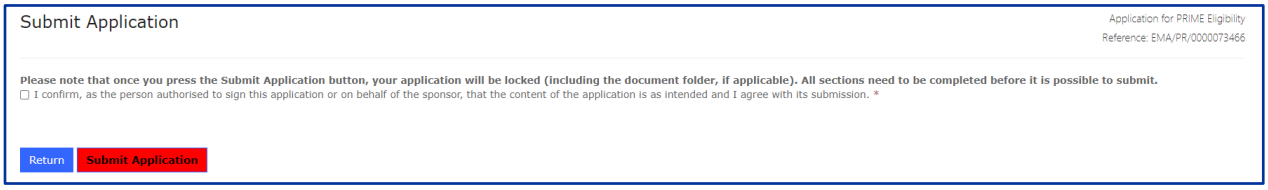


- Any additional comments on the submission can be included in section **"Submission Notes".**
- In section **"Documents from Applicant"**, the following documentation should be uploaded, named according to the naming conventions below:
  - PRIME eligibility request – Applicant's justification: the file name should be composed as follows: PRIME eligibility submission number (e.g., EMA/PR/0000001234) – RPI number – request justification.
  - References: the file (Zip) name should be composed as follows: PRIME eligibility submission number (e.g., EMA/PR/0000001234) – RPI number – references
  - Any additional documentation may be submitted by clicking on the "Add" button.
  - You may wish to generate a Word file copy of the Application Form by clicking on the "Generate Application Form" button at the bottom of the "Submission Form" page. The file will appear automatically in the "Documents from Applicant" section.
  - Please confirm that you have uploaded all documents that may be relevant to the submission.

After the outcome of the PRIME eligibility application is finalised, the Outcome Letter will become available in the section **"Documents from EMA"**.

- Please make sure that the required sections have a green tick to the right (except from "Documents from EMA") before **submitting the application**.

Figure 60. Submitting Application



You may review your draft application before submitting by clicking on the "Review Application" button in the pop-up box.

To see the status of your PRIME Eligibility applications (draft and submitted), go to the IRIS home page, click on the **"Submission"** tab and choose one of the three sub-tabs:

- on the "**Draft submissions**" sub-tab you can see a list of all your draft applications; from here you can edit, delete, view/manage the managers, contributors and contact person for each draft application before finalising the submission.
- on the "**Ongoing submissions**" sub-tab you can see a list of all your ongoing submissions and the evaluation status of the submitted case; from here you can edit, view/manage the managers, contributors, and contact person for each submission.

- on the "**Completed Submissions**" sub-tab you can view of all your completed submissions, the outcome and change the submission contact person.

Click on the drop-down arrow tab to perform all above modifications.

10.2. Transfer of a PRIME regulatory entitlement

Step-by-step guidance on how to create a submission, please refer to the generic steps described in section 2.3.

For process specific step, please follow the steps below:

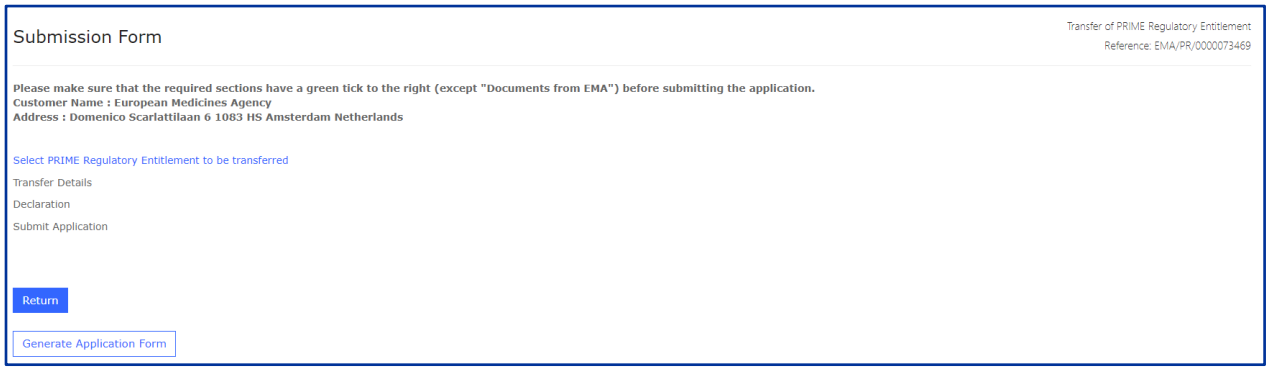
1. When choosing submission type, click on the magnifying glass symbol in the drop-down list and type in a keyword (e.g., PRIME) or the process type you wish to apply for (**e.g. Transfer of PRIME Regulatory Entitlement**) and then on "Select"; click "Create and Next".

Figure 61. New Draft Submission

2. Click "**Continue to Submission Form**".

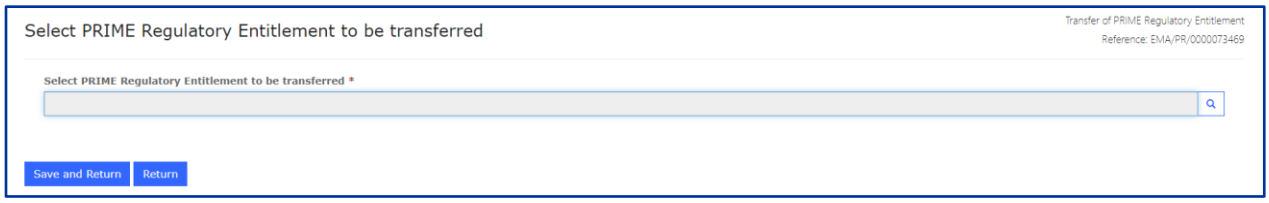
There is a Submission form list of four steps (tabs) starting with "**Select PRIME Regulatory Entitlement to be transferred**" and ending with "**Submit Application**" relating to your **"Transfer of PRIME Regulatory Entitlement"** application; the application reference number will contain PR (e.g., EMA/PR/0000001234) and displayed on the upper right-hand side of your screen;

Figure 62. Submission Form steps



3. In section "**Select PRIME Regulatory Entitlement to be transferred**", use the search symbol to look up the number of the PRIME Regulatory Entitlement to be transferred and then click on "Select"; click "Save and Return".

Figure 63. Select PRIME Regulatory Entitlement to be transferred



4. In section "**Transfer Details**", use the search symbol to look up the details of the new organization to which the PRIME Regulatory Entitlement will be transferred.

Figure 64. Transfer Details

5. In section "**Declaration**", tick the box to confirm as the person authorised to submit this application or on behalf of the applicant, that the content of the application is accurate and agree to the submission.

Figure 65. Declaration

6. Please make sure that all the required sections have a green tick to the right before submitting the application.

You may generate a Word file copy of the Application Form by clicking on the "**Generate Application Form"** button at the bottom of the "**Submission Form**" page. The file will appear automatically in the

Please note that once you press the Submit Application button, your application will be locked.

Should you wish to **withdraw** your "**Transfer of PRIME Regulatory Entitlement**" application, you may do so from the "**Ongoing submissions**" sub-tab by clicking on the drop-down arrow tab on the right-hand side of your application (View/Edit Submission option).

10.3. Withdrawal of a PRIME regulatory entitlement

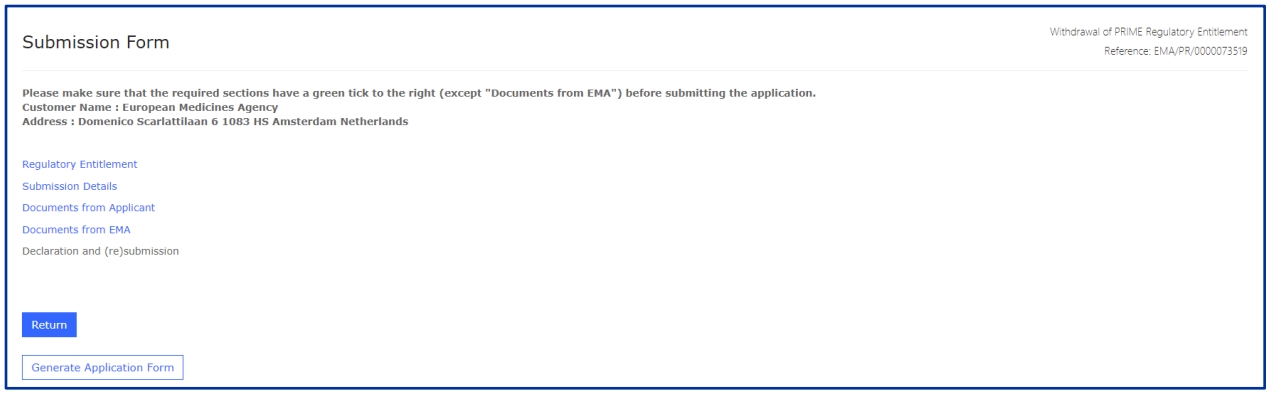
Step-by-step guidance on how to create a submission, please refer to the generic steps described in section 2.3.

For process specific step, please follow the steps below:

1. When choosing submission type, click on the magnifying glass symbol in the drop-down list and type in a keyword (e.g., PRIME) or the process type you wish to apply for (**e.g., Withdrawal of PRIME Regulatory Entitlement**) and then on "Select"; click "Create and Next".

There is a Submission form, list of five steps (tabs) starting with "**Regulatory Entitlement**" relating to your "Withdrawal of PRIME Regulatory Entitlement" application.

Figure 66. Submission Form steps



2. In section "**Regulatory Entitlement**", use the search symbol to look up the number of the PRIME Regulatory Entitlement to be withdrawn and then click on "Select"; click "Save and Return".
3. In section "**Submission Details**", it is mandatory to provide a brief explanation detailing the reasons for the submission of the withdrawal of this regulatory entitlement.
4. In section "**Documents from Applicant**", please upload any documents that may be relevant to the submission.
5. Please make sure that all the required sections (except from "Documents from EMA") have a green tick to the right before submitting the application.

You may generate a Word file copy of the Application Form by clicking on the "Generate Application Form" button at the bottom of the "**Submission Form**" page. The file will appear automatically in the "**Documents from Applicant**" section.

Please note that once you press the Submit Application button, your application will be locked (including the document folder, if applicable). You may review your draft application before submitting by clicking on the "Review Application" button in the pop-up box.

Should you wish to **withdraw** your "**Withdrawal of PRIME Regulatory Entitlement**" application, you may do so from the "**Ongoing submissions**" sub-tab by clicking on the drop-down arrow tab on the right-hand side of your application (View/Edit Submission option).

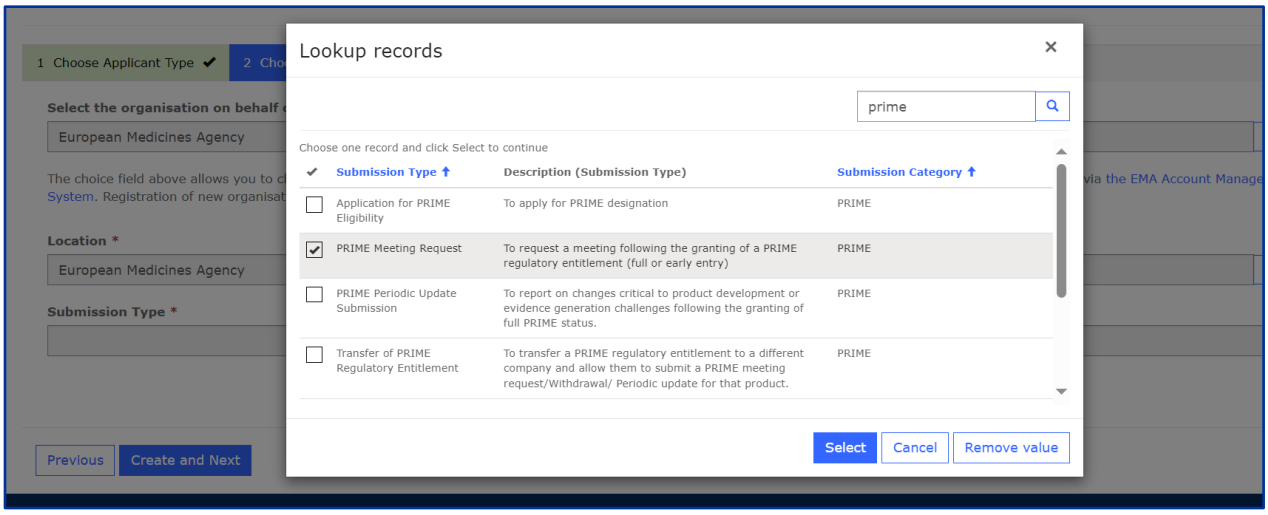
10.4. Submission of a PRIME meeting request

Step-by-step guidance on how to create a submission, please refer to the generic steps described in 2.3.

For process specific step, please follow the steps below:

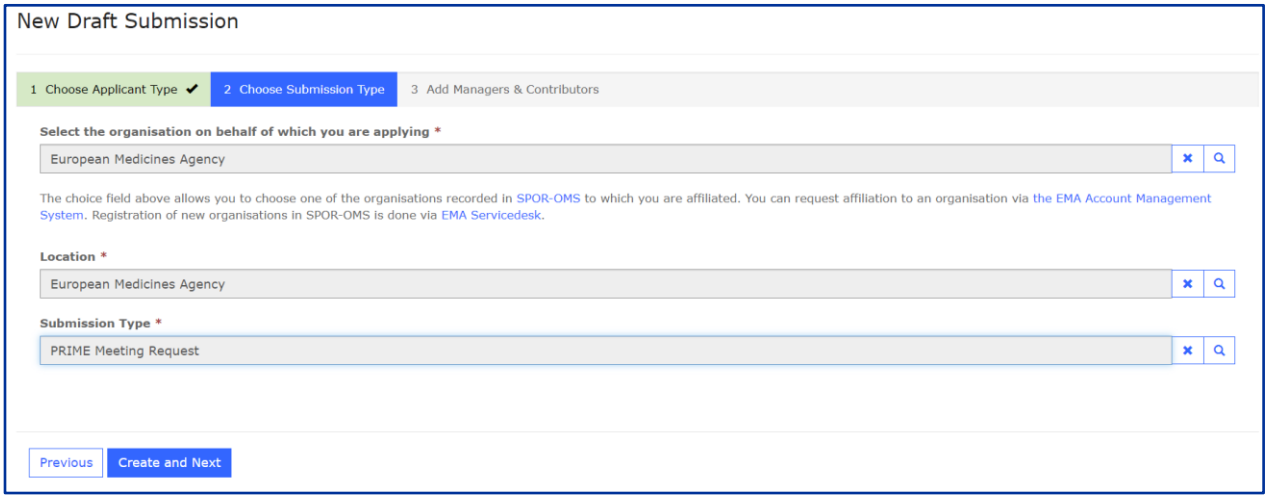
1. When choosing the submission type, **“2. Choose Submission Type”** click on the magnifying glass symbol in the drop-down list and type in a keyword (e.g., PRIME) or the process type you wish to apply for (e.g. **PRIME Meeting request**).

Figure 67. Select Submission Type



2. Once all three fields in step 2 are selected click “Create and Next”.

Figure 68. Submit Submission Type



3. In the Submission form there is a list of four steps (tabs) starting with **“Meeting Information”** and ending with **“Submit Application”** relating to the PRIME Meeting Request displayed on the left-hand side of your screen.

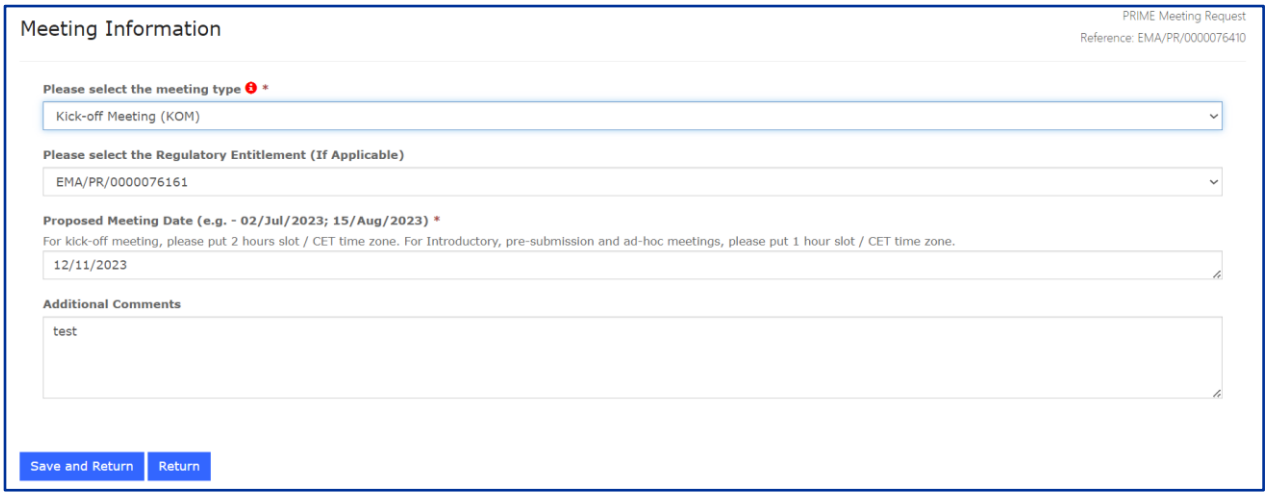
Figure 69. Submission from steps

4. In the "**Meeting Information"** tab, you need to choose the correct meeting type (Kick Off Meeting (KOM), Introductory meeting, Ad-hoc meeting, Submission readiness meeting and Pre-submission meeting).

Figure 70. Submission from steps - Meeting information

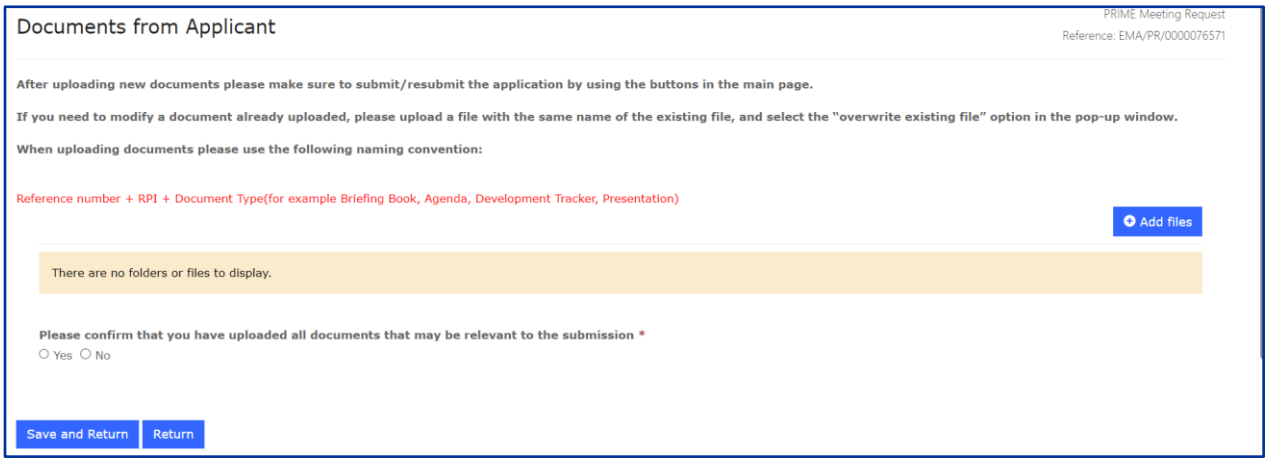
5. In the next steps, you need to first select the relevant (if any) **PRIME Regulatory Entitlement**, propose up to 5 possible **dates** for the meeting and add any **additional comments**. Kick-Off meeting and submission readiness meeting can only be requested if there is a full PRIME designation on the product. For early entry PRIME designations, please select Introductory meeting type. Ad-hoc meeting can be requested if the applicant has any type of PRIME regulatory entitlement, regardless of the type. Pre-submission meeting request is not inked to any regulatory entitlement.

Figure 71. Submission From steps – Meeting information



6. In the "**Documents from Applicants"** tab, you need to submit all relevant documentation for the requested meeting. Please follow the naming convention as Reference number + RPI + document type. For example: EMA/PR/0000076571 - PRD/0001234 – Briefing Book

Figure 72. Submission from steps – Documents from Applicant



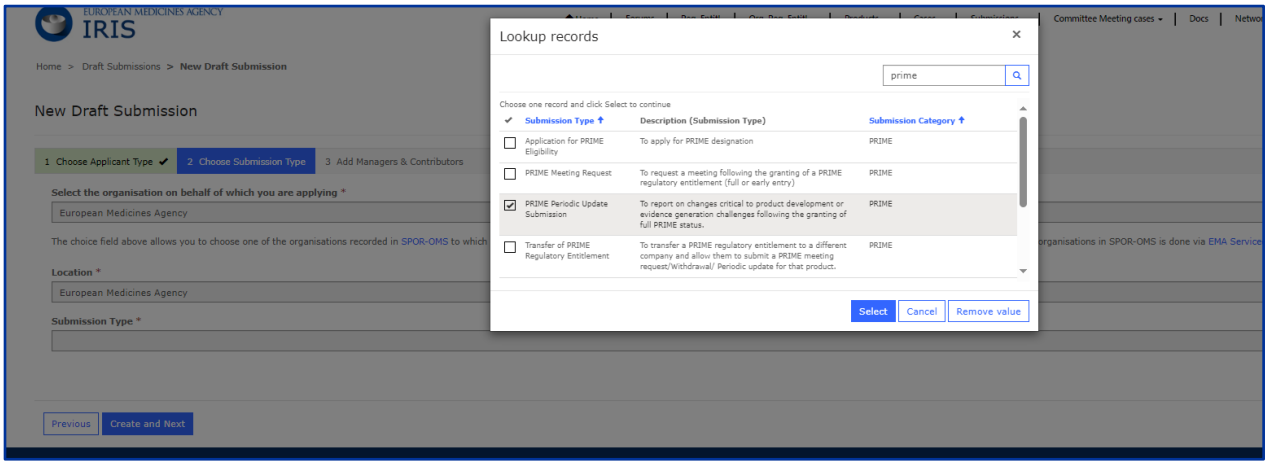
10.5. Submission of a PRIME periodic update

Step-by-step guidance on how to create a submission, please refer to the generic steps described in section 2.3.

For process specific step, please follow the steps below:

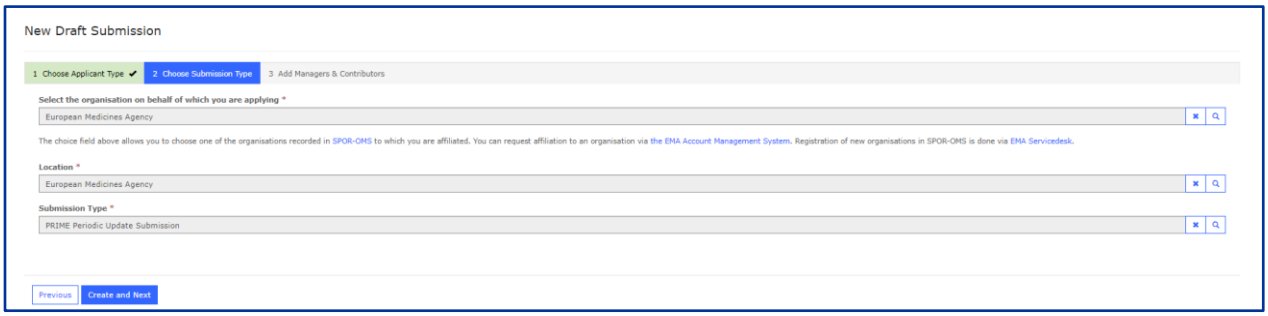
1. When choosing the submission type, **"2. Choose Submission Type"** click on the magnifying glass symbol in the drop-down list and type in a keyword (e.g., PRIME) or the process type you wish to apply for (e.g. **PRIME Periodic Update Submission**).

Figure 73. Select Submission Type



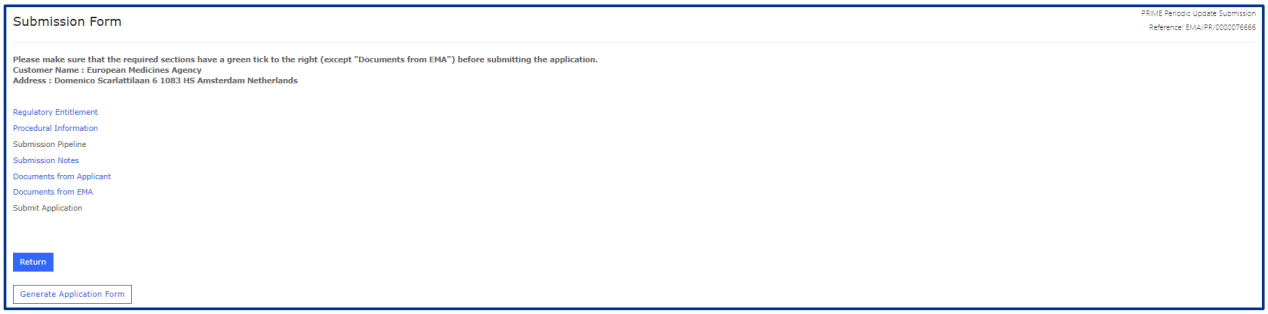
2. Once all three fields in step 2 are selected click “Create and Next”.

Figure 74. Submit Submission Type



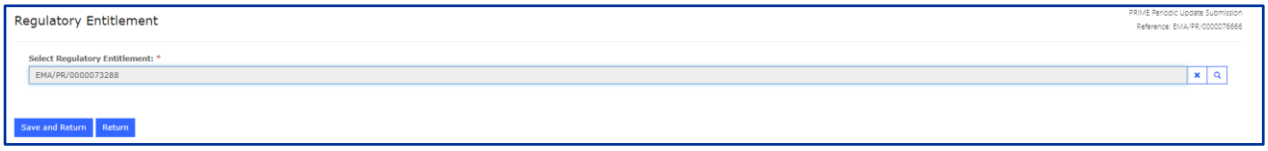
3. In the Submission form there is a list of seven steps (tabs) starting with **“Regulatory Entitlement”** and ending with **“Submit Application”** relating to the PRIME periodic update submission displayed on the left-hand side of your screen.

Figure 75. Submission form steps



4. In the “**Regulatory Entitlement”** tab, you need to choose the correct regulatory entitlement for which you wish to submit the periodic update and proceed to the next step by clicking on save and return.

Figure 76. Submission form steps – Regulatory Entitlement



5. In the "**Procedural Information"** tab, you need to indicate if *development is still ongoing* for the designated product/indication. In case the development is discontinued, the reasons must be explained in the next field called *"Reasons for discontinuation of development"*, which is a free text field. If PIP has been agreed the *PIP number* should be indicated in the next field. In case *scientific advice* has been received since the last periodic update, this must be recorded in the next section, by indicating the advice number. Finally, if *expedited advice* is requested with the submission of the periodic update, the area and some details must be explained in the last two free text fields. Please note that the expedited scientific advice referred to in the periodic update is a separate procedure and this request will have to be separately submitted.

Figure 77. Submission form steps – Procedural Information

6. In the "**Submission pipeline"** tab, the system displays **submission pipeline information** that is recorded on PRI "Information on Submission Pipeline (Please note this is read only from RPI)". Please check this information and, if changes are applicable to the either the MAA submission date or the legal basis, update in the "Update Information on Submission Pipeline" section and provide explanation for the proposed change in the free text box. Please note that any changes made in these fields will result in also updating the information of the RPI record.

Figure 78. Information on Submission Pipeline

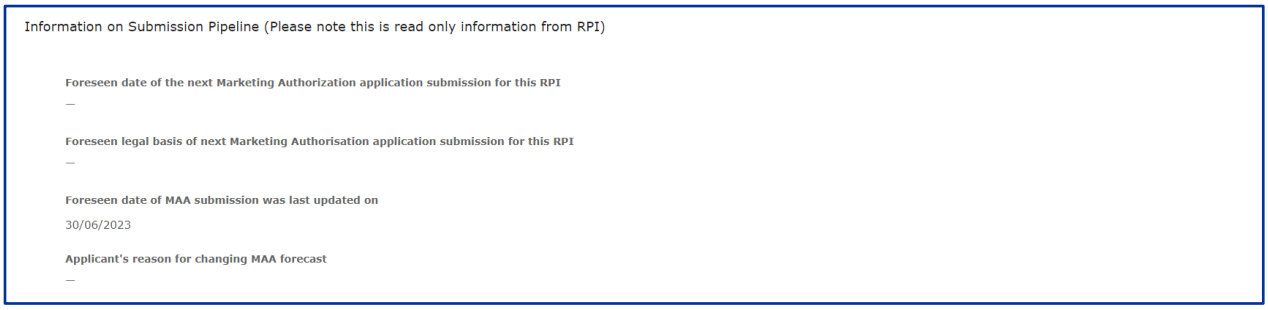
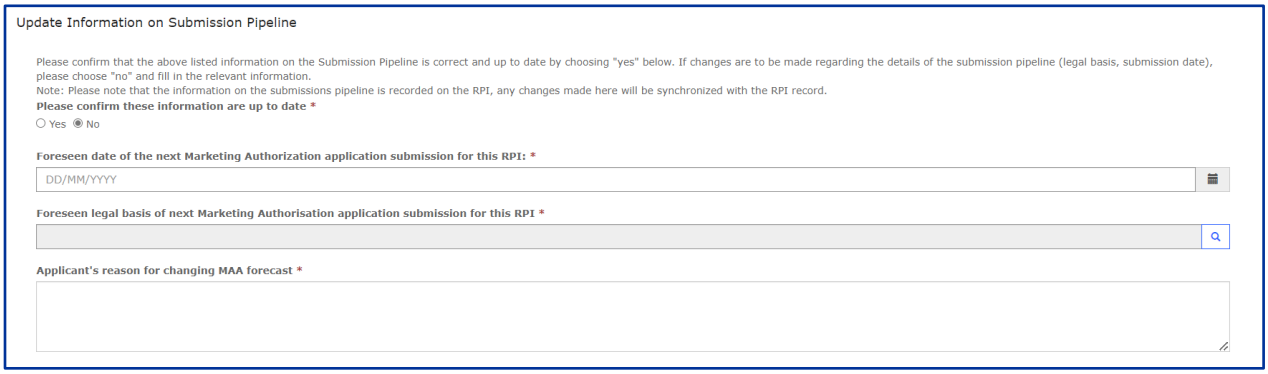


Figure 79. Update Information on Submission Pipeline



7. Once all the other steps have been completed the application can be submitted by the authorised person as for the other PRIME related procedures.

Figure 80. Submitting the application

11. Parallel distribution notifications

Domain applicability: human & veterinary

11.1. Purpose and context

This section of the guide is intended for parallel distribution applicants. More information on parallel distribution can be found in Frequently asked questions about parallel distribution | European Medicines Agency (europa.eu).

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 and RPIs which can be found on the IRIS guidance webpage.

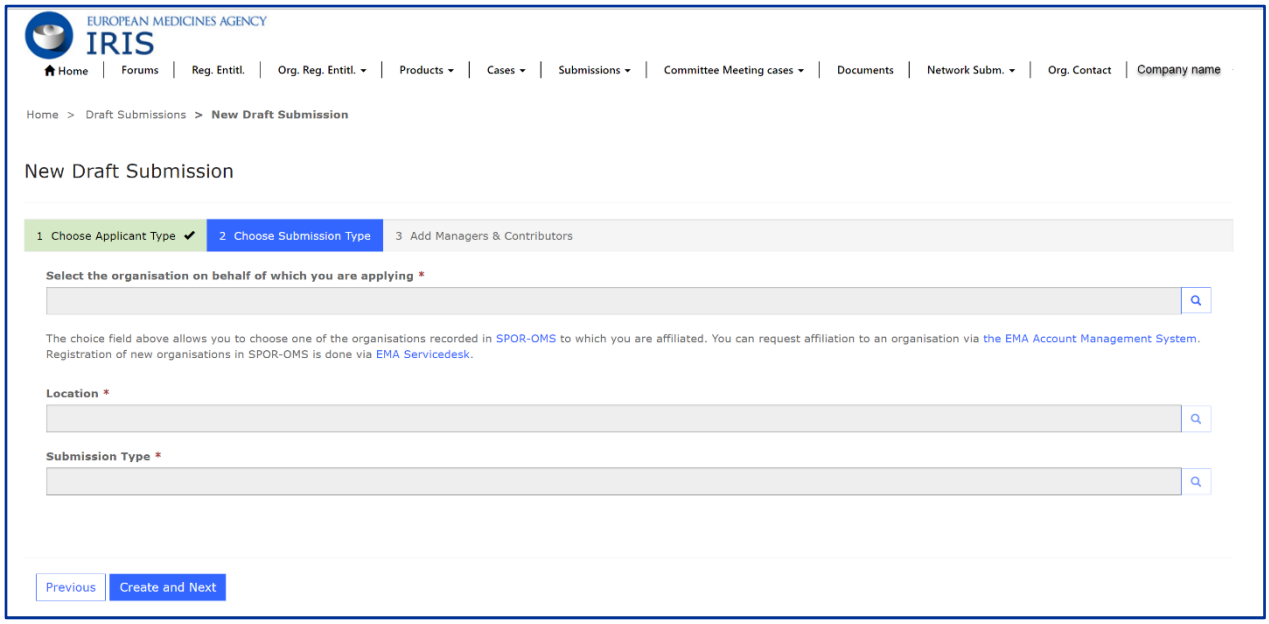
11.2. Create an application for parallel distribution

In addition to the steps in the general procedure as described in Section 2.3 "Create a new submission (general procedure for all submission types, except PLM procedures)", select the necessary parallel distribution submission as the submission type, Figure 81. New Draft Submission.

Note the following additional points:

- The reference number will contain PD (e.g. EMA/PD/0000001234) for your draft submission displayed on the upper right-hand side of the screen;
- Each submission screen will display a list of steps displayed on the left-hand side of your screen, each of which will be followed by a 'green tick' once completed (see Figure 81. New Draft Submission);

Figure 81. New Draft Submission



11.3. 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, a '**IRIS Parallel distribution Manager**' role through the EMA Account Management portal.

1. Follow the steps in section 2.3;Create a new submission (general procedure for all submission types, except PLM procedures)", see Figure 82. Submission Form;
2. Click on "**Parallel Distributor Information**" to bring up a screen on which to enter a Purchase Order number or a Reference number (limited to 35 characters) 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**";
3. 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";**
4. 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;
5. Click on "**Member States of Origin and Destination**" to indicate the MSO(s) and MSD(s) by clicking "**Add**" in each category;
6. 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**";

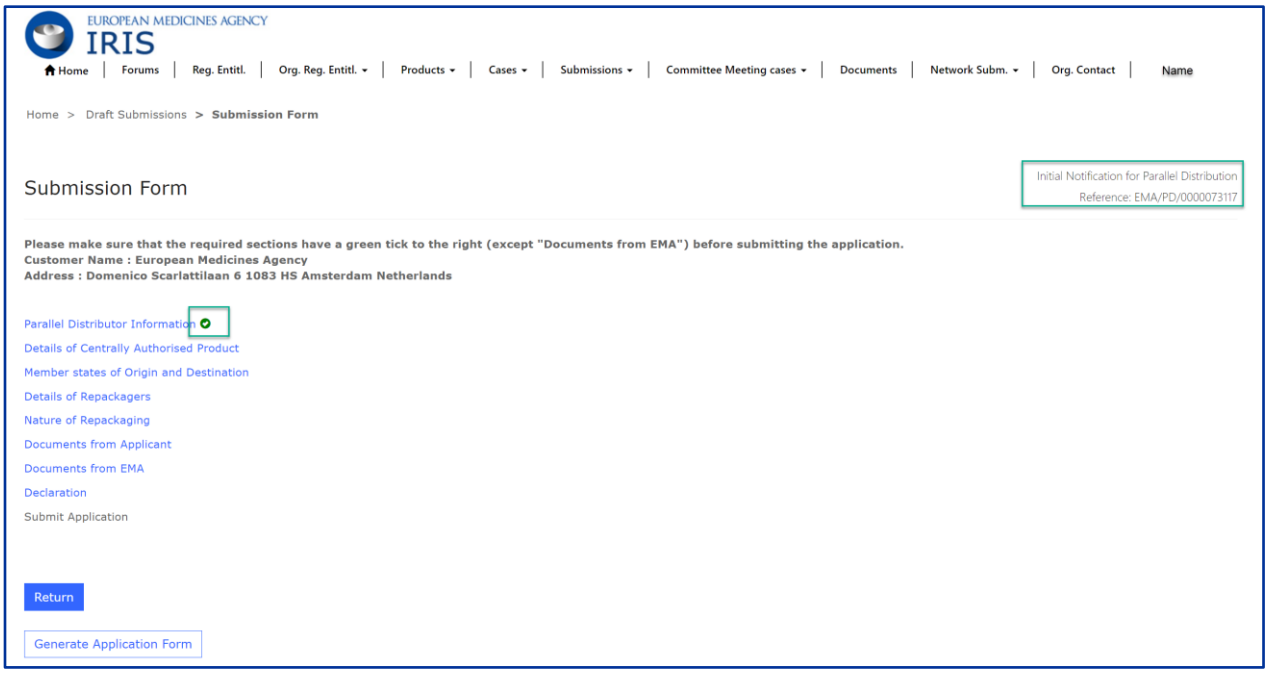
7. Click on "**Details of Repackagers**" and search for the relevant organisation(s) by clicking **"Add"**. The manufacturing and import authorisation number(s) should be added in the field provided below. Click "**Save and Return**"; N.B. At least one of the repackagers must hold a Manufacturing Importation Authorisation (MIA) licence with secondary repackaging authorised and the address of that repackager must correspond to the manufacturing site address of that MIA.
8. 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");
9. 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**";
10. Back in the main "Submission Form" page, click on "**Documents from Applicant**"; click on "**Add files**" to upload the documents; the pop-up window that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA.
11. 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).
12. 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.
13. Confirm with a "Yes" that the listed documents have been provided and click "**Save and Return**";
14. 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;
15. When you want to add more information, click on "**Submissions**"; then "**My Draft submissions**" and find the draft submission you want to edit;
16. Click on the downward arrow on the right-hand side and select "**Edit Draft**" from the drop-down list;
17. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
18. Repeat steps 14-16 until you are ready for final submission;

19. When you are ready to submit your final application, click on "**Declaration**" and confirm all the statements; click "**Save and Return**";

20. 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;

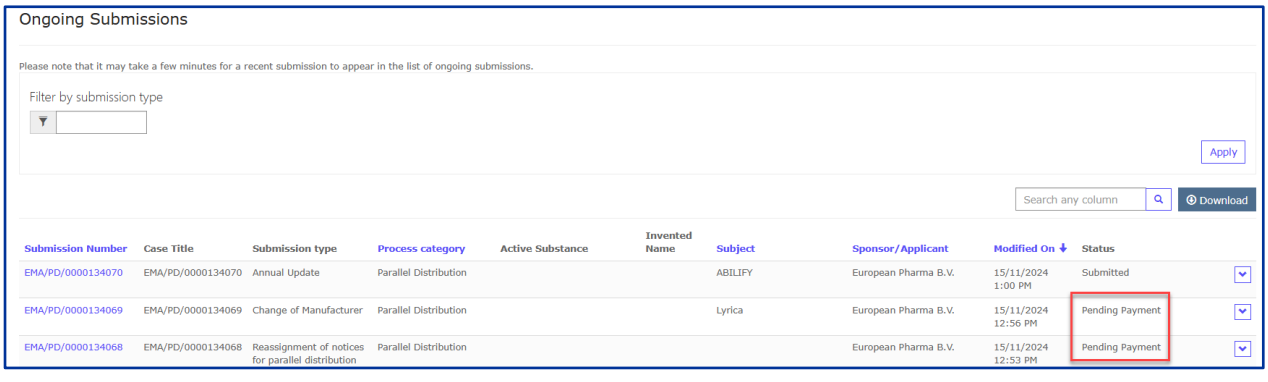
21. If you are unsure or think of any part of the application you want to revise, click "**Review Application**" and this will return you to the draft submission; If you are sure you want to submit the application, click "**Submit**".

Figure 82. Submission Form



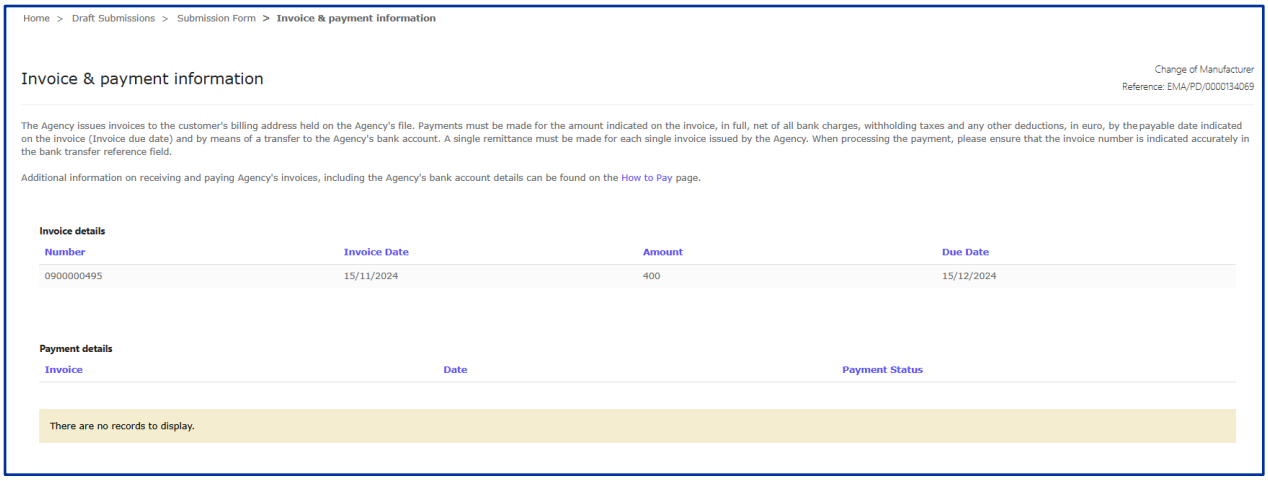
1. Your intention to submit a parallel distribution notification has now been received by the EMA and an email notification with guidance related to payment has been issued to you. Your submission has been assigned status "Pending payment". The submission in IRIS is now locked for edit unless EMA opens it up again for you to add any information.

Figure 83(a). Submission Form



2. You are returned to" Ongoing Submissions" page where you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Please open the submission and visit "Financial information" page on the form which has just been created and which contains payment-related information

Figure 83(b). Submission Form



3. Please note that the submission will be acknowledged, and the regulatory check will begin only after the payment has been received in full.
4. Once the payment has been received, the submission will move to the status "Payment received".
5. If the payment is not received within the deadline specified in the invoice, the submission is cancelled automatically with the status "Cancelled – payment not received" and is moved to "Completed Submissions" section.

Draft submissions and submissions already finalised by the Agency can be found in "My Draft Submissions" and "Completed Submissions" respectively.

11.4. Create an annual update for parallel distribution

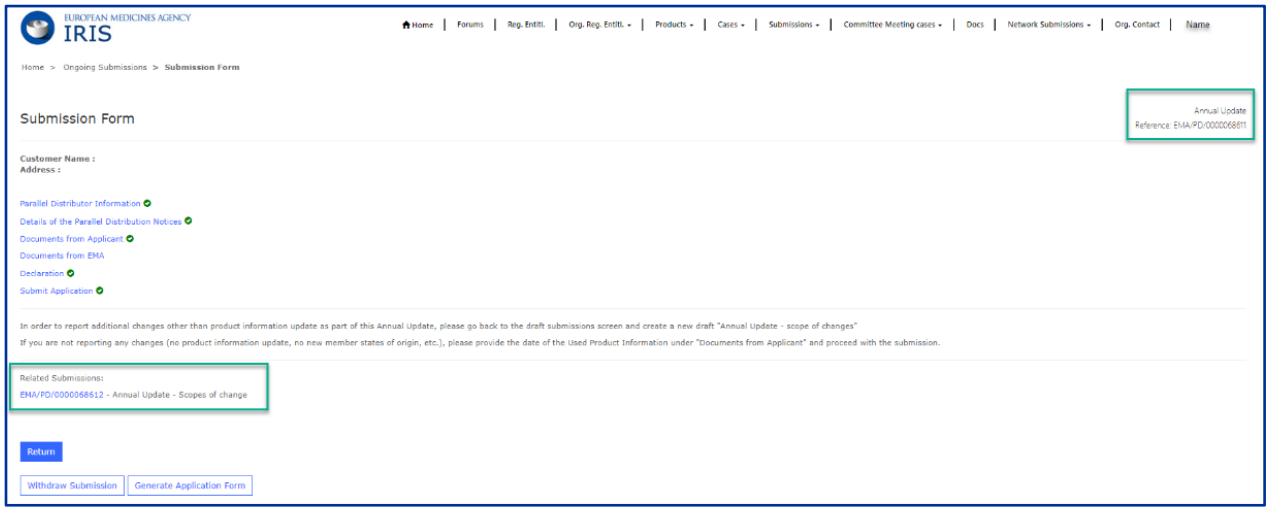
Follow the steps in section 2.3 "Create a new submission (general procedure for all submission types)", then see Figure 83. Submission Form;

1. A reference number (e.g. EMA/PD/0000001**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);
2. Click on "**Parallel Distributor Information**" to bring up a screen on which to enter a Purchase Order number or a Reference number (limited to 35 characters) 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**";

3. Click on "**Details of the Parallel Distribution Notices**" and search for the Product name 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)).
4. Click "**Yes**" or "**No**" in the field "Are you informing the EMA of any changes to the selected notices?", then click "**Return**";
5. In the "**Documents from Applicant**" folder add documents via **"Add files"** button. The pop-up window[3] that appears (SharePoint document repository) shows the secure Sharepoint folder in which your documents will be accessed by EMA
6. 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).
7. 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.
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).

[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.*

Figure 83. Submission Form



12. Your intention to submit a parallel distribution notification has now been received by the EMA and an email notification with guidance related to payment has been issued to you. Your submission has been assigned status “Pending payment". See Figure 83(a). The submission in IRIS is now locked for edit unless EMA opens it up again for you to add any information.

13. You are returned to ”Ongoing Submissions” page where you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Please open the submission and visit “Financial information” page on the form which has just been created and which contains payment-related information. See Figure 83(b).

14. Please note that the submission will be acknowledged, and the regulatory check will begin only after the payment has been received in full.

15. Once the payment has been received, the submission will move to the status “Payment received”.

16. If the payment is not received within the deadline specified in the invoice, the submission is cancelled automatically with the status “Cancelled – payment not received” and is moved to “Completed Submissions” section.

11.5. Notifying scopes of changes in an annual update

1. Back in the Draft Submissions, follow the steps in section 2.3 “Create a new submission (general procedure for all submission types)” 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), see Figure 84. Submission Form;

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 Repackegers/ 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/000000**1111**), 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, see Figure 84;

12. To proceed with the submission, click on "**Submit application**" and tick relevant statement(s), then click "**Declaration and submission**", then "**Submit**";

Figure 84. Submission Form

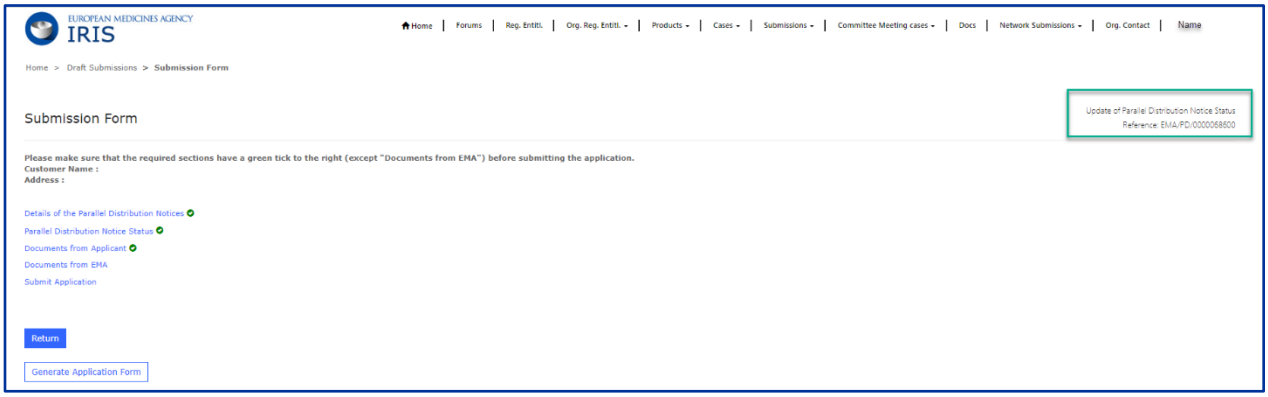
11.6. Create an update of parallel distribution notice status

Follow the steps in section 2.3 “Create a new submission (general procedure for all submission types)”, then see Figure 85. Submission Form;

1. 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;
2. 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’**;
3. 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’**;
4. 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;
5. When you want to add more information, click on “**My submissions**”; then “**Draft submissions**” find the draft submission you want to edit;
6. 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;
7. Repeat steps “2” to “4” until you are ready for final submission;
8. Click on the “**Submit Application**” button;
9. Confirm the declaration(s) and then click “**Declaration and Submission**”;
10. 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;

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

Figure 85. Submission Form



11.7. Create change of name and/or address on notices for parallel distribution

N.B. Before changing company name and/ or address on parallel distribution noticesin IRIS, please request a change in OMS (refer to the OMS guide in *IRIS guide to registration*)

1. Follow the steps in section 2.3 "Create a new submission (general procedure for all submission types)", then see Figure 86. Submission Form;

   Remember to select the correct submission type in the search box ("**Change of name and/or address on notices for parallel distribution"**)

2. Click on "**Parallel Distributor Information"** to bring up a screen with your Purchase order number (limited to 35 characters) and customer account number; fill those in (your customer number will be provided by the system in the field "Customer account number"). If the customer account number is correct, please confirm it with a "Yes"; if the number is incorrect or missing, click on "No" and enter the correct customer account number in the field "Please provide customer account number".

3. Click on "Save and Return";

4. 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 where the notices will be moved to;

5. A field "New name and/or address" updates once the information has successfully been entered. Click "**Save and return**";

6. Click "**Submission details**" – this will open a window to add any information or clarifications relevant to the change. Click "**Save and return**";

7. Click “**Documents from Applicant**” and via “**Add files**” button attach the relevant documents (e.g. new WDA), confirm the upload, click “**Save and return**”;
8. “**Documents from EMA**” will contain documents from EMA (if applicable);
9. Click “**Declaration**”, confirm the statements, click “**Save and return**”;

   Click “**Submit Application**”; confirm the declaration(s) and then click “**Declaration and submission**”;
10. 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. If you are sure you want to submit the application, click on ”**Submit**”.

You are returned to ”Ongoing Submissions” page where you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Please open the submission and visit “Financial information” page on the form which has just been created, and which contains payment-related information. See Figure 86.

Figure 86. Submission Form

12. Your intention to submit a parallel distribution notification has now been received by the EMA and an email notification with guidance related to payment has been issued to you. Your submission has been assigned status “Pending payment". See Figure 83(a). The submission in IRIS is now locked for edit unless EMA opens it up again for you to add any information.
13. Please note that the submission will be acknowledged, and the regulatory check will begin only after the payment has been received in full.
14. Once the payment has been received, the submission will move to the status “Payment received”.
15. If the payment is not received within the deadline specified in the invoice, the submission is cancelled automatically with the status “Cancelled – payment not received” and is moved to “Completed Submissions” section.

11.8. 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 in section 2.3 “Create a new submission (general procedure for all submission types)”, then see Figure 88. Submission form
2. Click on “**Parallel Distributor information**” to bring up a screen for your Purchase order number (limited to 35 characters) and customer account number; 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**”;
3. Click “Save and Return”;
4. Click on “Select Parallel Distribution Notices” and “Select All Notices”; click “Save and Return”;
5. In “Add or Remove Repackagers” screen add and remove repackages as necessary in the relevant fields; click “**Save and return**”;
6. Click “**Documents from Applicant**” and via “**Add files**” button attach the relevant documents (e.g. new licence), confirm the upload, click “**Save and return**”;
7. “**Documents from EMA**” will contain documents from EMA (if applicable);
8. Click “**Declaration**”, confirm the statement, click “**Save and return**”;
9. Click “Submit Application”.
10. Confirm the declaration(s) and then click “**Declaration and Submission**”;
11. 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; If you are sure you want to submit the application, click ”**Submit**”.

Figure 87. Submission Form

12. Your intention to submit a parallel distribution notification has now been received by the EMA and an email notification with guidance related to payment has been issued to you. Your submission has been assigned status “Pending payment". See Figure 83(a). The submission in IRIS is now locked for edit unless EMA opens it up again for you to add any information.
13. You are returned to ”Ongoing Submissions” page where you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Please open the submission and visit “Financial information” page on the form which has just been created and which contains payment-related information. See Figure 83(b).
14. Please note that the submission will be acknowledged, and the regulatory check will begin only after the payment has been received in full.
15. Once the payment has been received, the submission will move to the status “Payment received”.
16. If the payment is not received within the deadline specified in the invoice, the submission is cancelled automatically with the status “Cancelled – payment not received” and is moved to “Completed Submissions” section.

11.9. 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 in section 2.3 “Create a new submission (general procedure for all submission types)”, then see Figure 88. Submission Form;
2. Click on “**Parallel Distributor information**” to bring up a screen for your Purchase order number (limited to 35 characters) and customer account number; 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**”;
3. Click on “**Reassignment Details**” and select the new company; click “**Save and return**”;
4. Click “**Documents from Applicant**” and via “**Add files**” button attach the relevant documents, confirm the upload, click “**Save and return**”;
5. “**Documents from EMA**” will contain documents from EMA (if applicable);
6. Click “**Declaration**”, confirm the statements, click “**Save and return**”;
7. Click “**Submit Application**”, confirm the declaration(s) and then click “**Submit Application**” – a **“Confirm Submission”** box will pop up;
8. 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; If you are sure you want to submit the application, click ”**Submit**”.

Figure 88. Submission Form

9. Your intention to submit a parallel distribution notification has now been received by the EMA and an email notification with guidance related to payment has been issued to you. Your submission has been assigned status “Pending payment". See Figure 83(a). The submission in IRIS is now locked for edit unless EMA opens it up again for you to add any information.
10. You are returned to ”Ongoing Submissions” page where you can now look up the submission you have just made by Submission ID, Submission type, product name, etc. Please open the submission and visit “Financial information” page on the form which has just been created and which contains payment-related information. See Figure 83(b).
11. Please note that the submission will be acknowledged, and the regulatory check will begin only after the payment has been received in full.
12. Once the payment has been received, the submission will move to the status “Payment received”.
13. If the payment is not received within the deadline specified in the invoice, the submission is cancelled automatically with the status “Cancelled – payment not received” and is moved to “Completed Submissions” section.

12. Product Lifecycle Management (PLM) procedures[4]

Domain applicability: human & veterinary

For general information on product lifecycle procedures, please consult the EMA website on relevant procedures.

The process of submitting all PLM procedures will not change and will still be performed via the current systems (i.e. Gateway and PSUR repository). For specific information on how to submit an application for PLM procedures, including the supporting documentation, please refer to Submitting a post-authorisation application | European Medicines Agency for human medicinal products and VET eSubmission for veterinary medicinal products on the EMA website.

For PLM procedures **there is no submission creation in IRIS by industry users**. The submissions will be created by EMA in IRIS based on the information presented in the electronic application form included in eCTD sequence or PSUR submission after technical validation. After submission is created in IRIS by EMA, it will be exposed to the industry portal under "Ongoing Submissions" sub-tab. The default Submission contact/Portal contact will receive a confirmation email once the submission has been created – see section 12.1.

For PLM procedures led by EMA, the default **Submission Contact/Portal contact** is:

For CAPs:

- the person authorised for communication with the Agency (see section 2.4.3 of the application form). For worksharing or grouped variations affecting more than one product, default Submission Contact/Portal contact is the contact of the lead MA Product as indicated by the Applicant in the Letter of Intent;

For NAPs (depends on the type of the procedure e.g. Referrals, PSURs):

- QPPV registered in Art 57 database or UPD;
- Regulatory contact point (RCP) registered in the Eudravigilance database (Human domain;
- MAH contact point at national level;
- MAH contact point assigned to the procedure by the MAH (e.g. Referral triggered by MAH).
- For PSURs, contact person indicated in the PSUR form (Human domain).

12.1. Display and sort submissions

Once a submission is created by EMA in IRIS, it will become visible for default submission contact (who is also a manager for that submission) under "**Ongoing Submissions**" sub-tab of the **"Submissions"** tab.

[4] variations and Art. 61(3) notifications under Directive 2001/83/EC, variations requiring assessment under Regulation 2019/6 and Marketing Authorisation transfer applications for human and veterinary medicinal products

For detailed information regarding “Submission Contact” (“Portal Contact”), please see section 2.4. of this guide.

Additional MAH IRIS users will be able to see the procedure/case after they are assigned with the roles IRIS Industry Manager or Contributor to that specific case by the default manager.

If you have an IRIS Industry Coordinator role, you will see all PLM procedures/cases and other IRIS submission types of your affiliated organisation(s).

In all cases , you will see the submissions only if you are affiliated to the correct organisation in IAM (see the “IRIS guide to registration and RPIs” for further details).

Click on any of the column headings that appear in blue font, and the rows listed in the table will be sorted in ascending order (click again for descending order).

See section 2.1 for further details.

12.2. Search for submissions

See section 2.2..

Please note information on “Draft Submissions” is not applicable for PLM cases.

12.3. Add contributors/managers to a PLM procedures

See sections 2.5. and 2.6.

12.4. Communication model and change submission contact person to a PLM procedures

See sections 2.4

12.5. Check the current status of PLM submissions in the IRIS Portal

See section 2.12

12.6. Withdrawal of a PLM procedure

For the step-by-step guidance on how to withdraw a full submission (all scopes), please refer to the generic steps described in section 2.8.

Please note for PLM procedures requesting of withdrawal of single scopes (not the full submission) continues to be communicated and agreed with EMA via email (See section 12.7)

In addition to withdrawing the case in IRIS, the MAH is required, as per current process, to submit an eCTD consolidation sequence. See also eCTD Guidance v4 0-20160318-hv (europa.eu), section 4.11 Applicant Withdrawal or Agency Rejections of Post-Authorisation Regulatory Activities.

12.7. Exchange of documentation and communication with EMA for PLM procedures (outside eCTD/VNeeS submissions)

On receipt of a notification email from EMA stating that further information is required for one of your Ongoing Submissions, for example a "Validation Supplementary Information (VSI)", please follow the instructions as indicated in the email.

If any changes/updates are needed to the submission data in IRIS, log into the IRIS portal and carry out the following steps:

a. From the IRIS home page, click on "**Ongoing submissions**" sub-tab present under "**Submission**" tab;

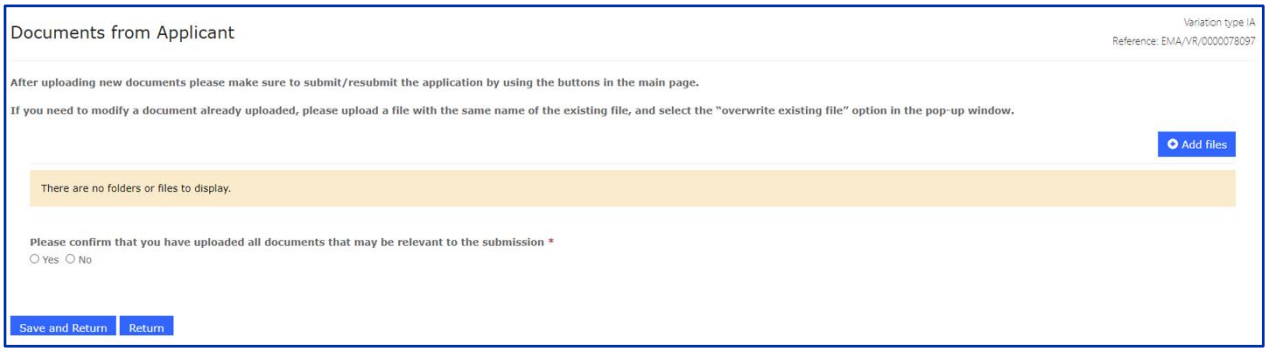
b. Locate the submission mentioned in the e-mail by using the sort or search features described in this Guide, or by just scrolling down the list until you find it;

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

d. If you need to upload any document, select "Documents from Applicant". Click on "Add files" and select as many documents as needed. Confirm that all documents have been uploaded and click on "Save and Return" when you are done.

e. Please note while there is no maximum number of files or global size, there is a size limit of 50 Mb per file. Please upload individual files for each document, rather than a single Zip file (or similar) for the set of all documents; it is possible to upload multiple files in a single operation. If appropriate, you can merge several PDF files into a single one, using specific software, before uploading. A Zip file is recommended only as the container for the literature references; all other documents should be submitted individually.

Figure 89. Uploading documents from Applicant



On receipt of a notification email from EMA stating for example that there is a new document uploaded by EMA for one of your Ongoing Submissions, log into the IRIS portal and carry out the following steps:

a. From the IRIS home page, click on "Ongoing submissions" sub-tab present under "Submission" tab;

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

c. At the right of the row in the list where your submission appears, click on the drop-down arrow and select “View/edit submission”;

d. The documents shared by EMA can be accessed in “Documents from EMA” folder.

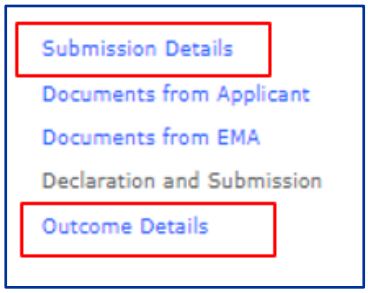
NOTE: When replying to the email sent from EMA, **do not** alter the subject line of the email. Keeping the email token in the subject (IRIS numbers at the end of the email subject) will associate that email to the relevant case in IRIS on EMA side).

12.8. Submission details and outcome information for PLM procedures

Main submission details and additional procedural information (e.g. Timetables, resources assigned to the submission etc.) can be found in the “Submission details” form clicking on the active submission number or by clicking on the drop-down arrow tab on the right-hand side of your submission (View/Edit Submission option).

Main outcome details for the procedures for which the Opinion or Notification have been issued by EMA can be found in the “Outcome details” form by clicking on the drop-down arrow tab on the right-hand side of your submission (View/Edit Submission option).

Figure 90. Submission details and outcome details



12.9. Steps after end of linguistic review

The linguistic review process itself does not change and stays outside IRIS. Day+5 submission of the EUPIs has to be performed via Eudralink. On a day+25 the MAH will upload the final translations and relevant documents via the Industry portal). Full translations timetable available via IRIS Industry portal. EMA will proceed with EPAR publications/EC decision process.

12.10. Re-examination

Process remains unchanged. The MAH will upload via the industry portal a letter to inform of the intention to request a re-examination within 15 days from the receipt* of the opinion. Once the detailed grounds for the re-examination have been received (within 60 days from the receipt* of the opinion), then the case will be managed according to the agreed timetable.

*A document shall be deemed received on the date the notification email is sent by the EMA to the MAH indicating that a new document is available in the IRIS portal. The foregoing is without prejudice to the provisions set out in Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits.

13. Paediatric medicines development

Domain applicability: human

For general information on paediatric medicine development, please consult the Paediatric medicines: Research and development section on the EMA website.

For specific information on how to prepare a paediatric submission and list of documents to be uploaded in the submission please refer to Procedural advice on paediatric applications guidance document.

Note: Mandatory fields are marked with a red asterisk "*" and must be completed in all pages for all type of applications.

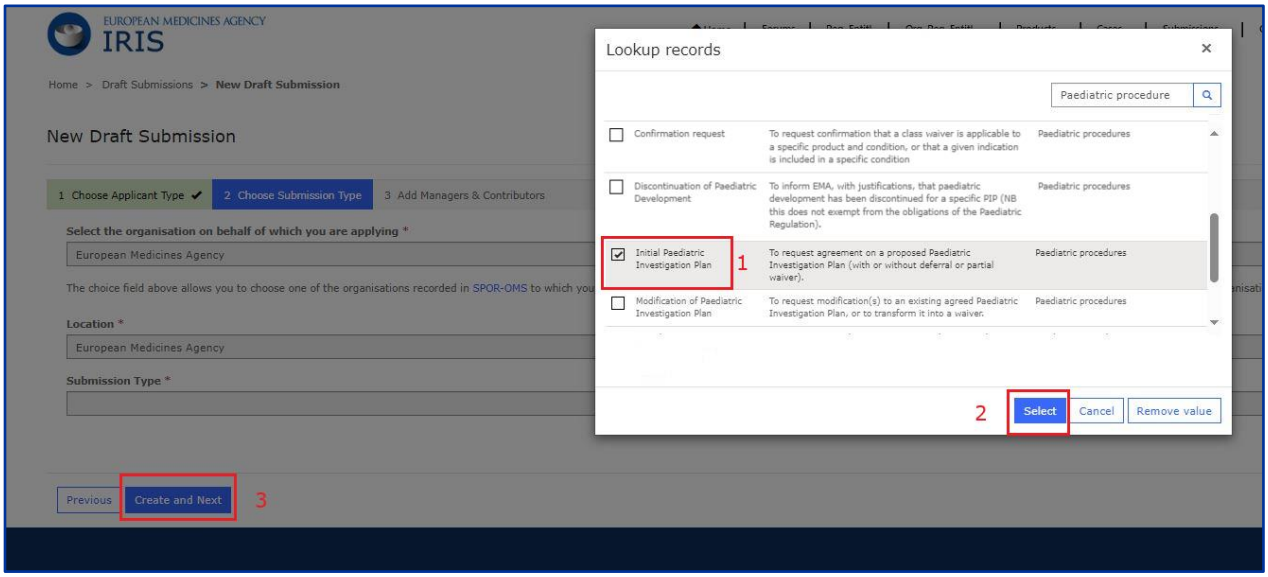
It is also important to ensure the correct submission type as this cannot be amended once the application has been submitted.

13.1. Create an application for initial paediatric investigation plan (PIP)

In addition to the above Section 2.3. "Create new submission"

1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
   - Chose "Initial Paediatric Investigation Plan" as Submission Type;
   - Click on "**Select**";
   - Click on "Create and Next".

Figure 91. Initial Paediatric Investigation plan submission



2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).

3. The **Submission Form** page will open where the reference number will contain **PE** (e.g. EMA/**PE**/0000001234) for your draft submission located displayed on the upper right-hand side.
4. There is a list of 10 sections (tabs) starting with "**Select OD/RPI**" and ending with "**Submit Application**" displayed on the left-hand side of your screen.

Figure 92. Submission form

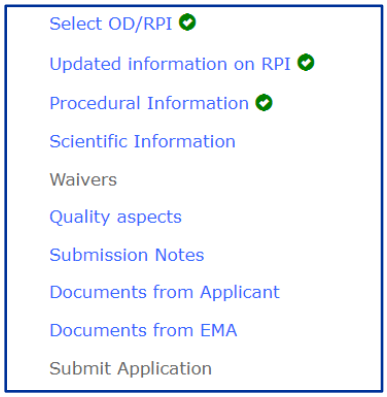
5. The section (tab) "**Select OD/RPI**" must be completed before the other sections (tabs) become available.
6. Complete all the mandatory fields and use the search field (RPI lookup) to select your product.
7. Click on "Save and Return".

Figure 93. Select OD/RPI

8. All required sections (tabs) in blue should be completed (except "Documents from EMA") before submitting the application.

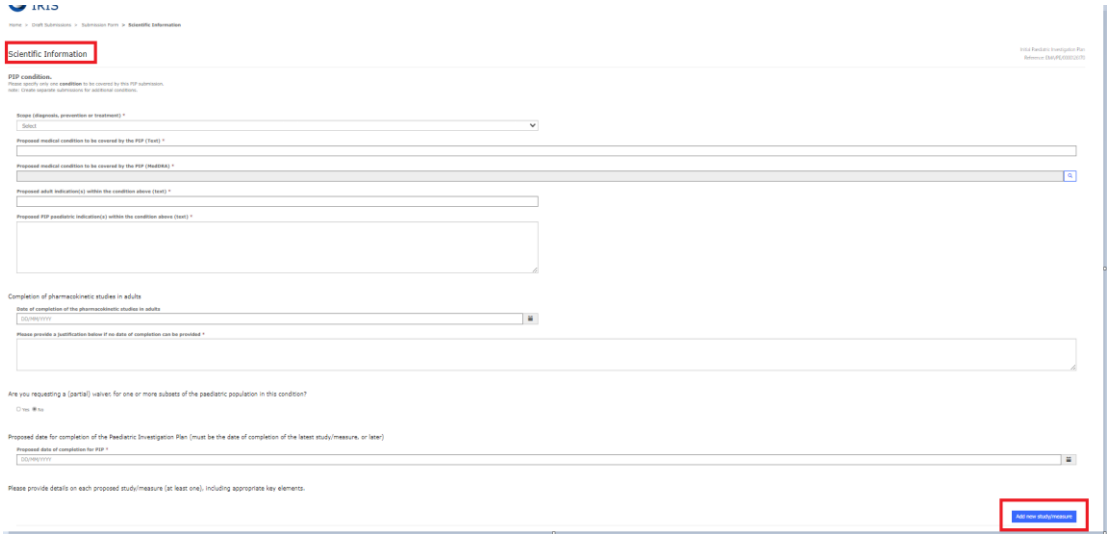
9. Some sections (tabs) may not be applicable (e.g. Waivers if not requested) and will remain grey.

Figure 94. Required completed sections (tabs)

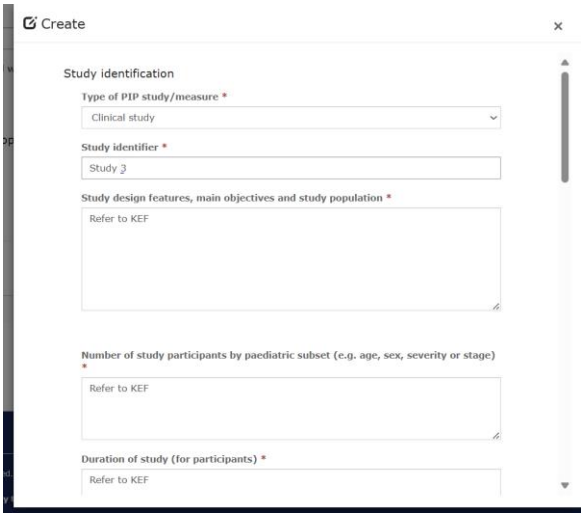


10. When completing "**Scientific Information"** section (tab), include each study type in IRIS but not all the details. Refer to the published Key Element form and the steps below:

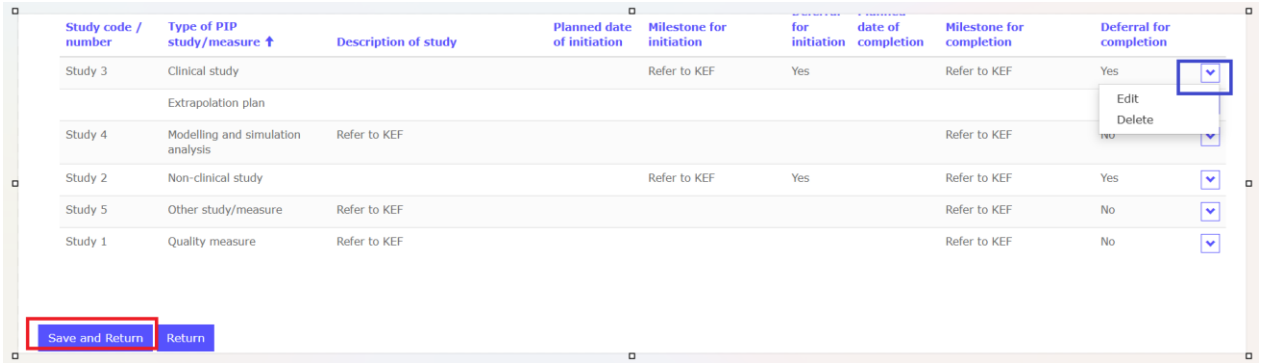
- In Scientific Information tab, press "**Add new study/measure"** button:



- Chose the type of Study/measure from the drop-down menu for all your studies, complete the Study identifier (if applicable) and answer deferral question Yes/No, add “Refer to KEF” in the mandatory text boxes then Save.

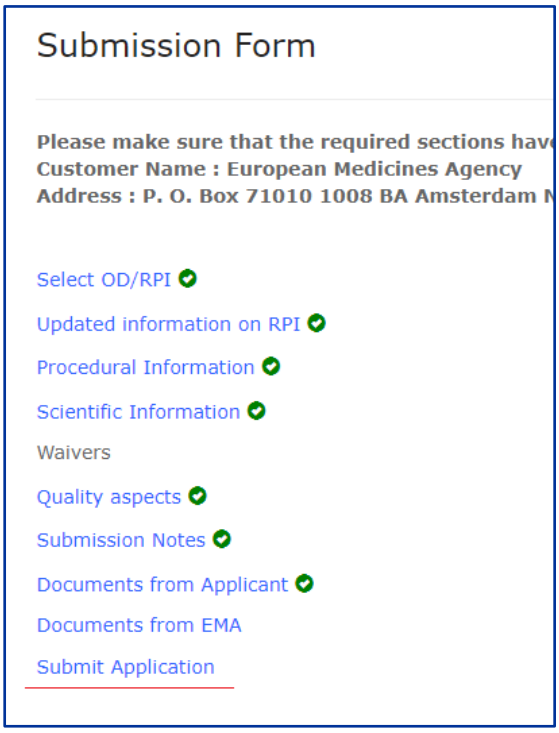


- List of studies will be summarised but not detailed as shown below. It is possible to edit or delete.



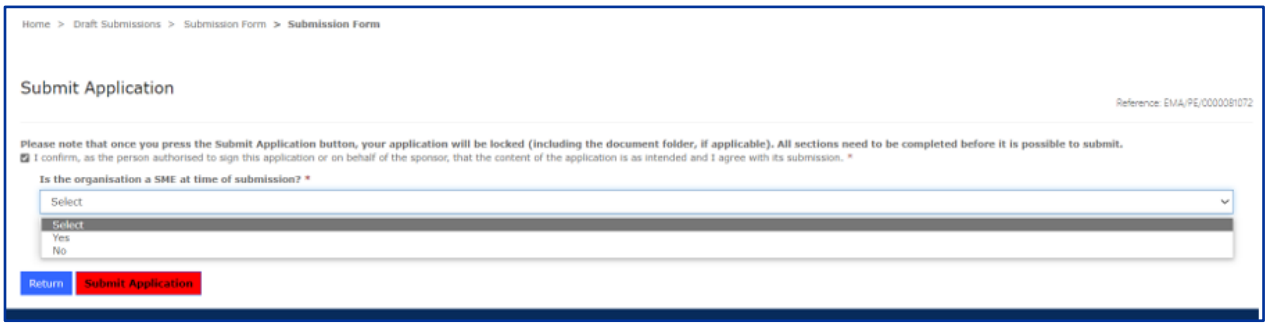
11. In section (tab) **“Submission Notes”** additional information can be added e.g. agreed specific timelines, information related to Stepwise PIP. Do not leave it empty, if not used type “N/A”.
12. Complete each required sections (tabs) ensuring that green tick to the right is displayed (except "Documents from EMA") then click on “**Submit Application”**.

Figure 95. Submit Application



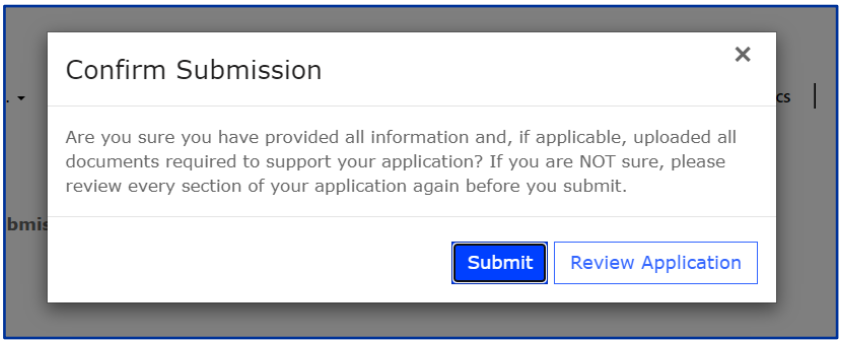
13. Confirm signature of the application and select the correct information from the drop down list.
14. Click on “**Return**” to go back or “**Submit Application**” for the next step.

Figure 96. Submit Application



15. A pop-up window will appear, giving you a final opportunity to check that all the details have been entered correctly by clicking on “**Review Application**”, or click on “**Submit**” when finished.

Figure 97. Confirm submission



16. If the application is not submitted yet, it will be saved as a Draft Submission that can be completed later. To retrieve your draft submission please refer to the above section **2.2. Search for submission**.
17. If the application is submitted, it will be displayed under Submissions tab in Ongoing Submissions subtab.

13.1.1. Submitting the response to Paediatric Committee request for supplementary information and modification of proposed PIP (RSI)

Should there be a PDCO request for modifications, refer to Procedural advice on paediatric applications for list of documents to be submitted.

In case key elements have only been submitted in IRIS before, please submit a word document including the changes using the latest published template ***Key elements form.***

1. Locate and open the initial PIP submission currently in clock-stop under your Ongoing Submissions and upload and submit the document using "Documents from Applicant" section (tab) and Submit application, complete the application similarly as in 13.1. (Figure 97).

Figure 98. Open ongoing submission

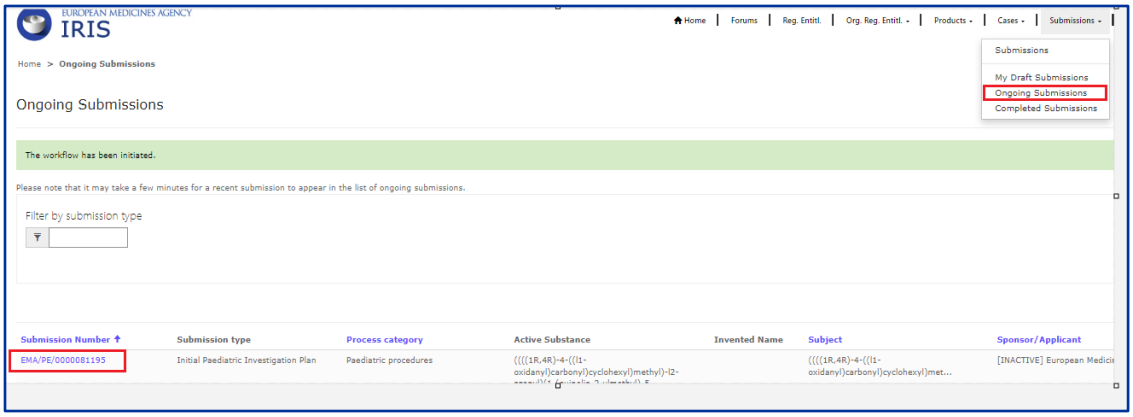
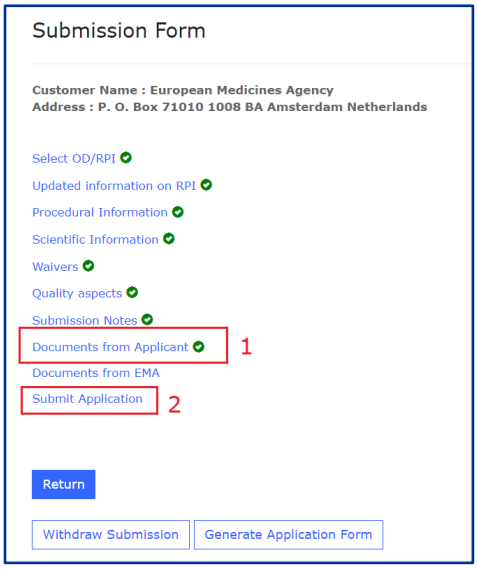


Figure 99. Upload documentation and complete submission



Amend the details in Scientific Information, Waivers and Quality aspects sections if applicable.

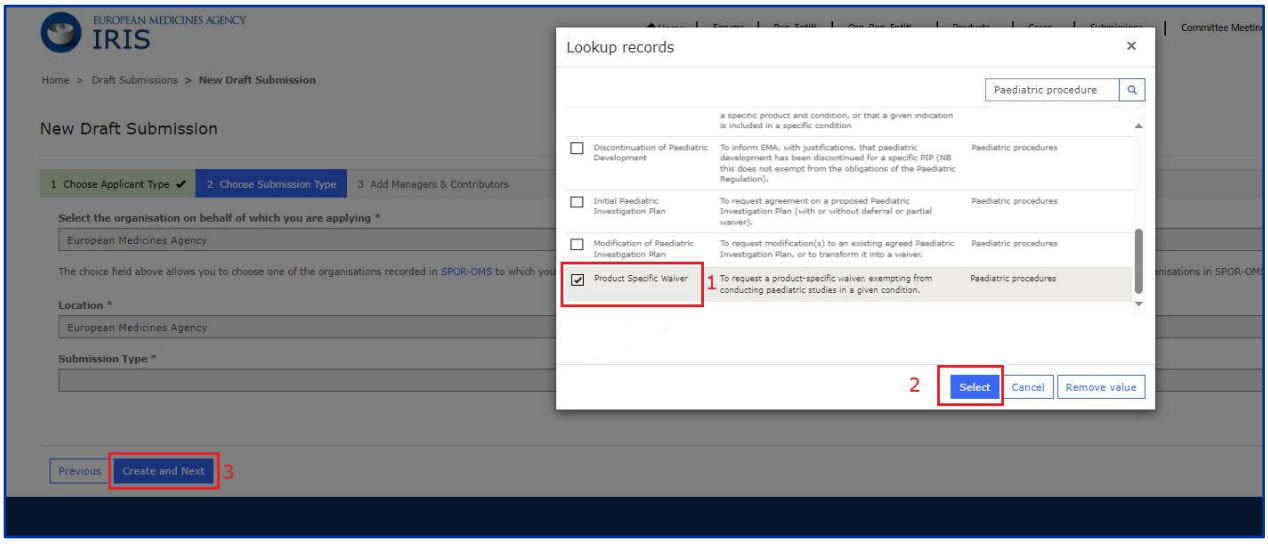
Important: Uploading documents itself is not a submission, it is necessary to complete this via "Submit Application"

13.2. Create an application for product specific waiver

In addition to the above Section 2.3. "Create a new submission":

1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
    - Chose **"Product Specific Waiver"** as the submission type;
    - Click on "**Select**";
    - Click on "Create and Next".

Figure 100. Product Specific Waiver submission



2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).
3. Follow the steps similarly as above in section 13.1.

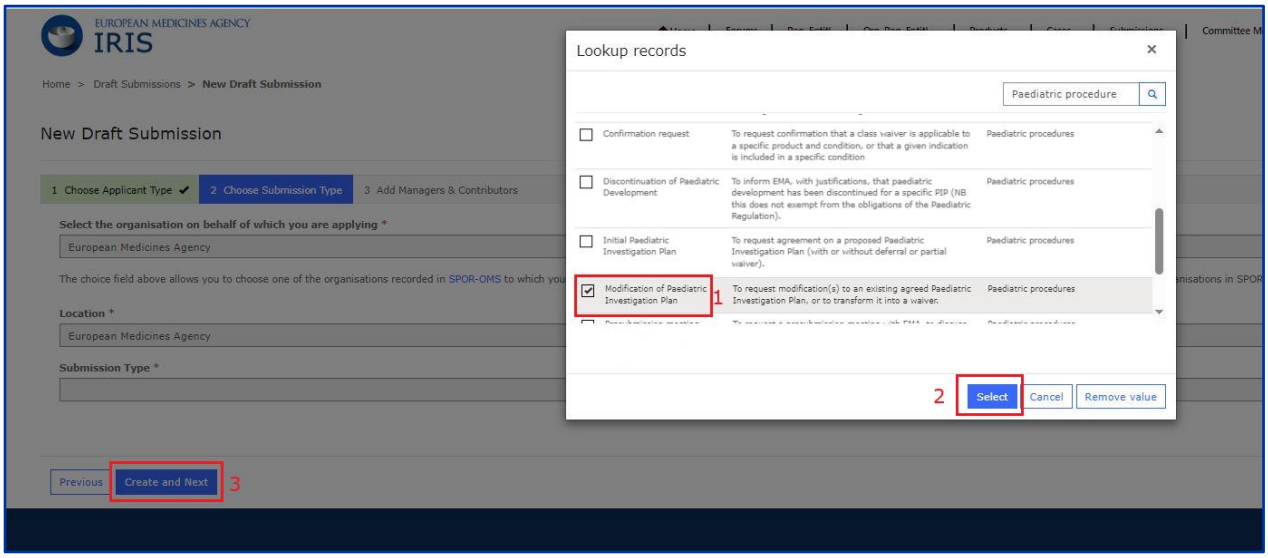
Note: Completion of Key elements will not be applicable for this procedure.

13.3. Create an application for modification of Paediatric Investigation Plan (modification of an agreed PIP)

In addition to the above Section 2.3. "Create a new submission":

1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
   - Chose "Modification of Paediatric Investigation Plan" as the submission type;
   - Click on "**Select**";
   - Click on "Create and Next".

Figure 101. Modification of Paediatric Investigation Plan submission



2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).

3. Follow the steps similarly as above in section 13.1. and note the following additional points:

   - Click-on "**Select Paediatric Regulatory Entitlement"** and select the relevant "**Entitlement Number**" from the Lookup records. (Figure 101) This section (tab) must be completed before other sections (tabs) become available.

Figure 102. Select Paediatric Regulatory Entitlement

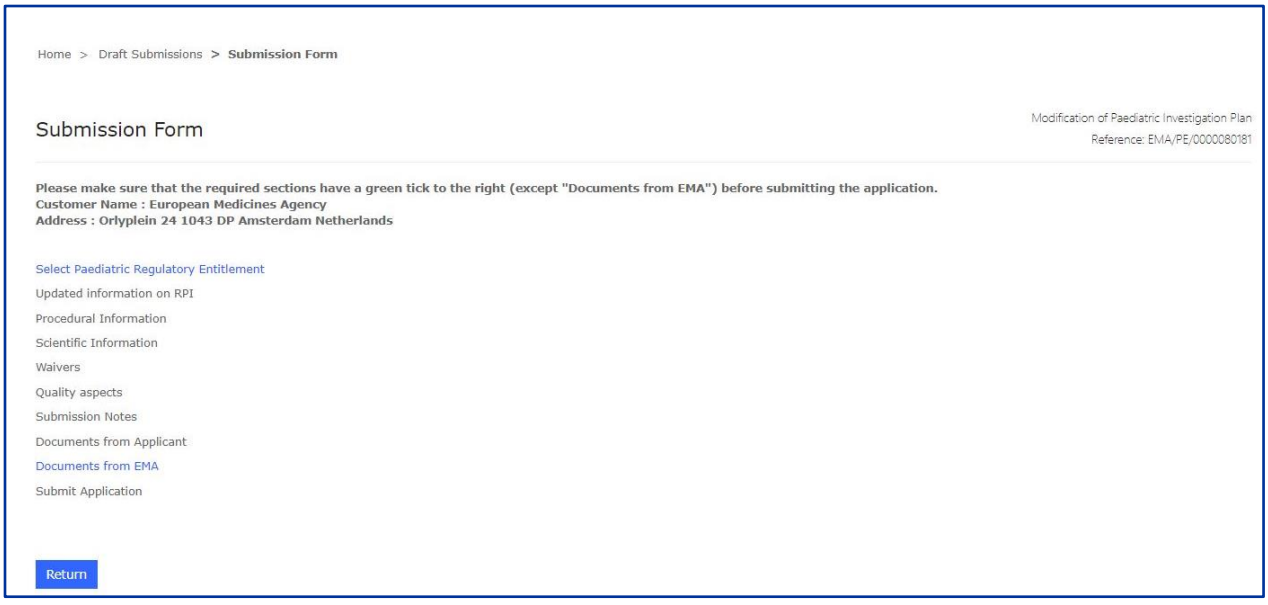
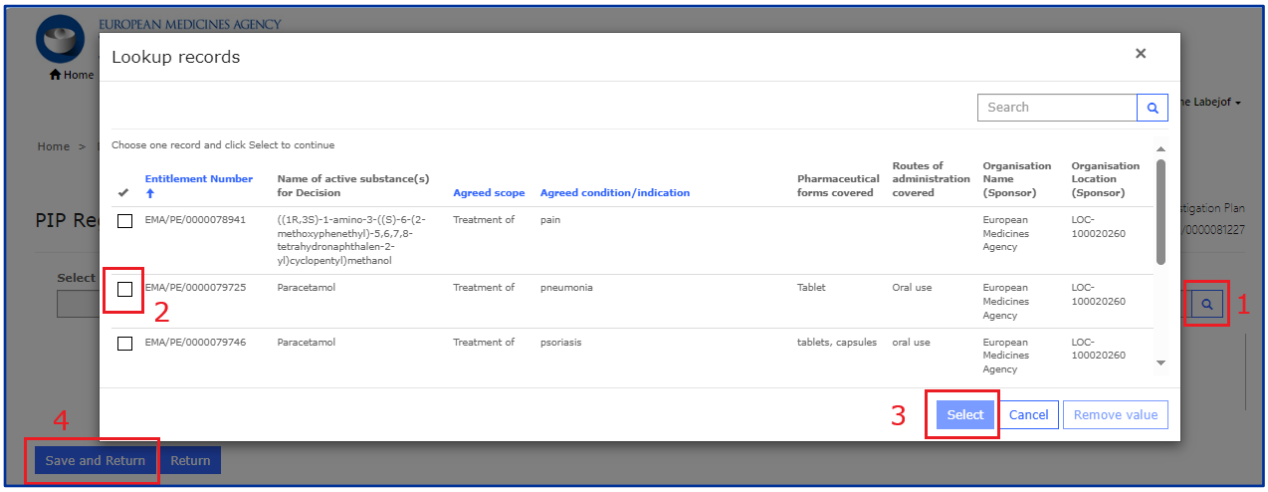


Figure 103. Entitlement number selection



Notes:

You must be the owner of the previous paediatric investigation plan “regulatory entitlement” (same LOC-ID); if not, the current owner must transfer the paediatric procedure Regulatory entitlement to the correct LOC-ID before you can request a modification (see “Transfer a paediatric regulatory entitlement” below).

Several fields will be prepopulated from the previously completed paediatric procedure case; some, such as the RPI cannot be edited.

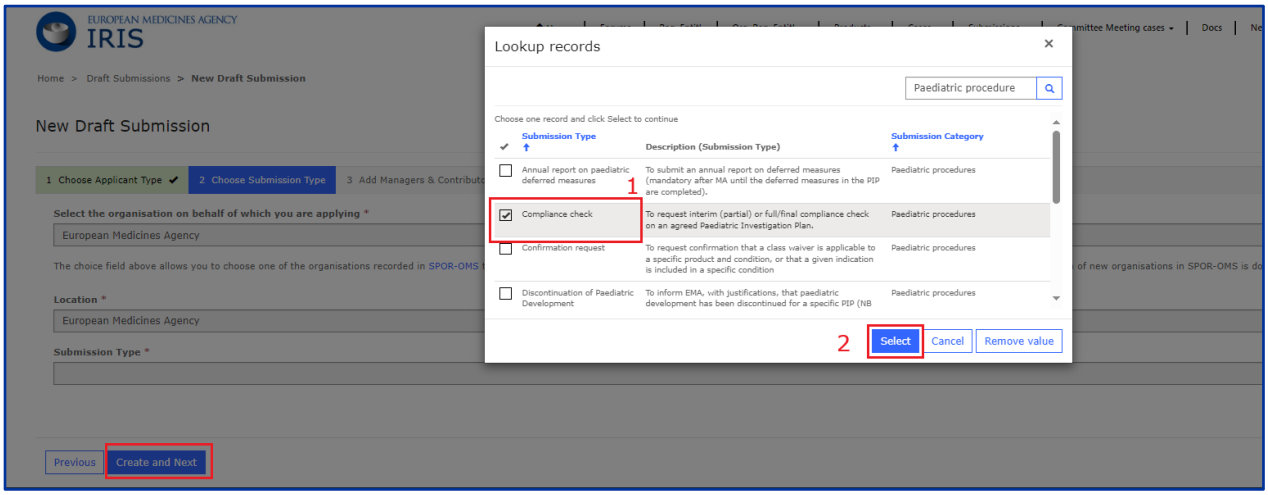
Key elements: include only the type of studies in IRIS and add “Refer to KEF” in the mandatory fields.

13.4. Create an application for compliance check

In addition to the above Section 2.3. “Create a new submission”:

1. Type “Paediatric procedure” in Lookup records (search field) which will display all process types for paediatric procedures:
    - Chose “**Compliance check**” as the submission type;
    - Click on “**Select**”;
    - Click on “Create and Next”.

Figure 104. Compliance check submission



2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).

3. Follow the steps similarly as above in section 13.1. and note the following additional points:

   - Click-on "**Select Paediatric Regulatory Entitlement"** and select the relevant "**Entitlement Number**" from the Lookup records (Figure 101). This section (tab) must be completed before other sections (tabs) become available.

Notes:

You must be the owner of the previous paediatric investigation plan "regulatory entitlement" (same LOC-ID); if not, the current owner must transfer the paediatric procedure Regulatory entitlement to the correct LOC-ID before you can request a modification (see "Transfer a paediatric regulatory entitlement" below).

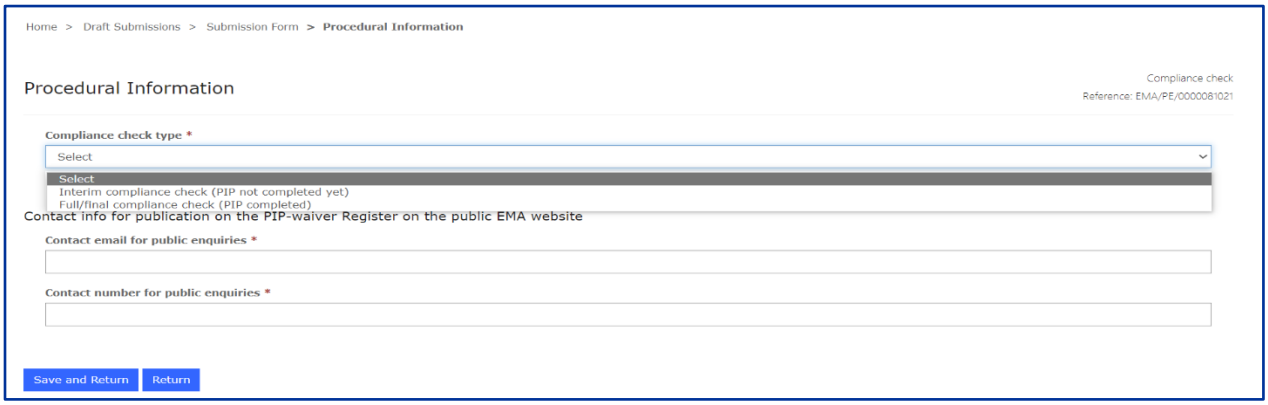
Several fields will be prepopulated from the previously completed paediatric procedure case; some, such as the RPI and cannot be edited.

- In "**Procedural information"** section (tab) choose the compliance check type:
- Interim compliance check (PIP not completed yet);

or

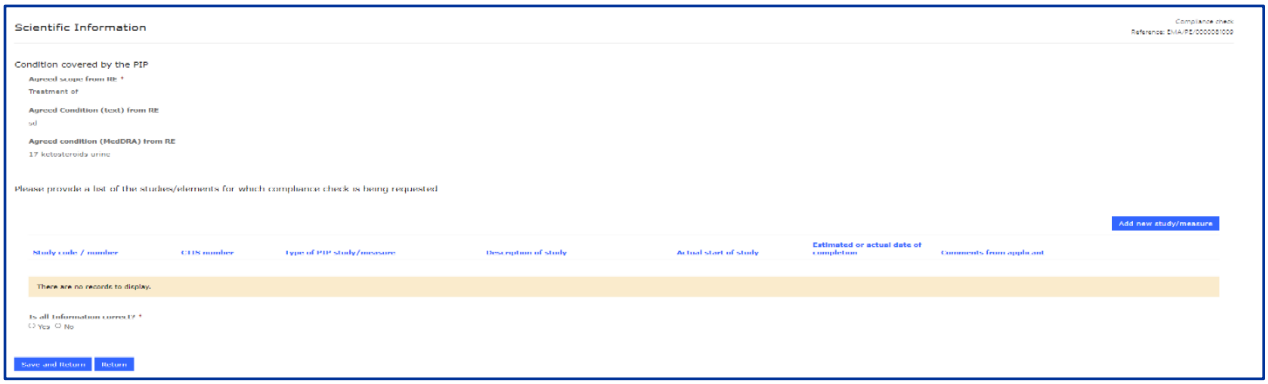
- Full/final compliance check (PIP completed).

Figure 105. Procedural Information – Compliance check



4. In "**Scientific Information"** section (tab) provide the list of studies for which compliance check is being requested.

Figure 106. Scientific Information – Compliance check



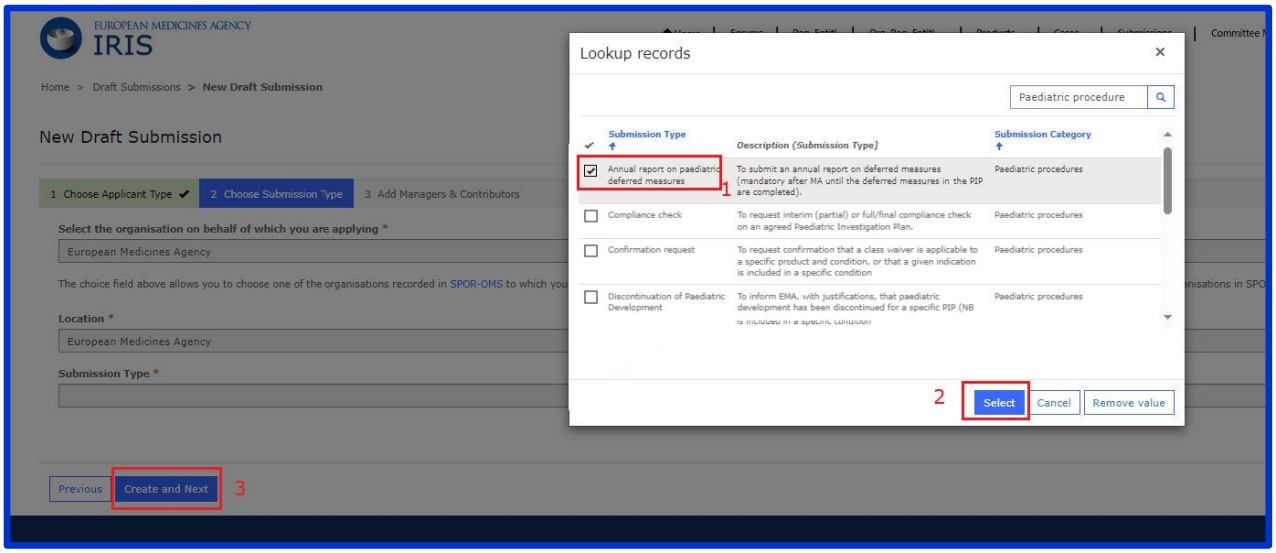
Note: Listing the key element and its location in the dossier to be checked should be provided in a separate document – refer to Procedural advice on paediatric applications.

13.5. Create a submission for annual report on paediatric deferred measures

In addition to the above Section 2.3. "Create a new submission":

1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
   - Chose "**Annual report**" as the submission type;
   - Click on "**Select**";
   - Click on "Create and Next".

Figure 107. Annual report on deferred measures submission



1. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).
2. Follow the steps similarly as above in section 13.1. and note the following additional points:
    - Click-on "**Select Paediatric Regulatory Entitlement"** and select the relevant "**Entitlement Number**" from the Lookup records (Figure 101). This section (tab) must be completed before other sections (tabs) become available.

Notes:

You must be the owner of the previous paediatric investigation plan "regulatory entitlement" (same LOC-ID); if not, the current owner must transfer the paediatric procedure Regulatory entitlement to the correct LOC-ID before you can request a modification (see "Transfer a paediatric regulatory entitlement" below).

Several fields will be prepopulated from the previously completed paediatric procedure case; some, such as the RPI and cannot be edited.

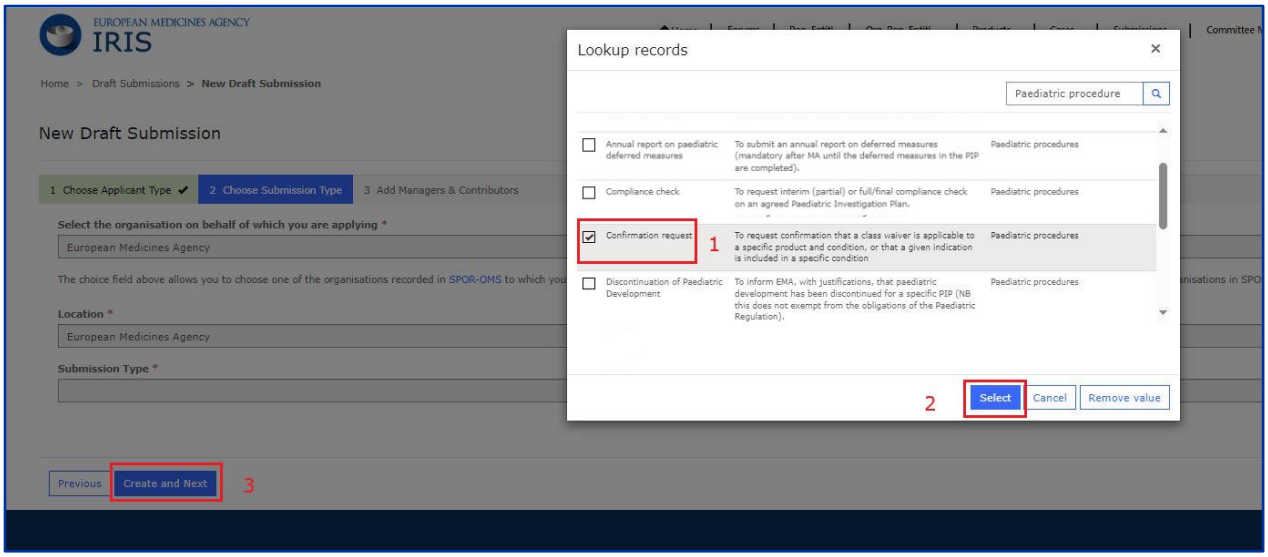
13.6. Other paediatric procedures

13.6.1. Create a submission for Confirmation request

In addition to the above Section 2.3. "Create a new submission":

1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
    - Chose "**Confirmation request**" as the submission type;
    - Click on "**Select**";
    - Click on "Create and Next".

Figure 108. Confirmation request submission

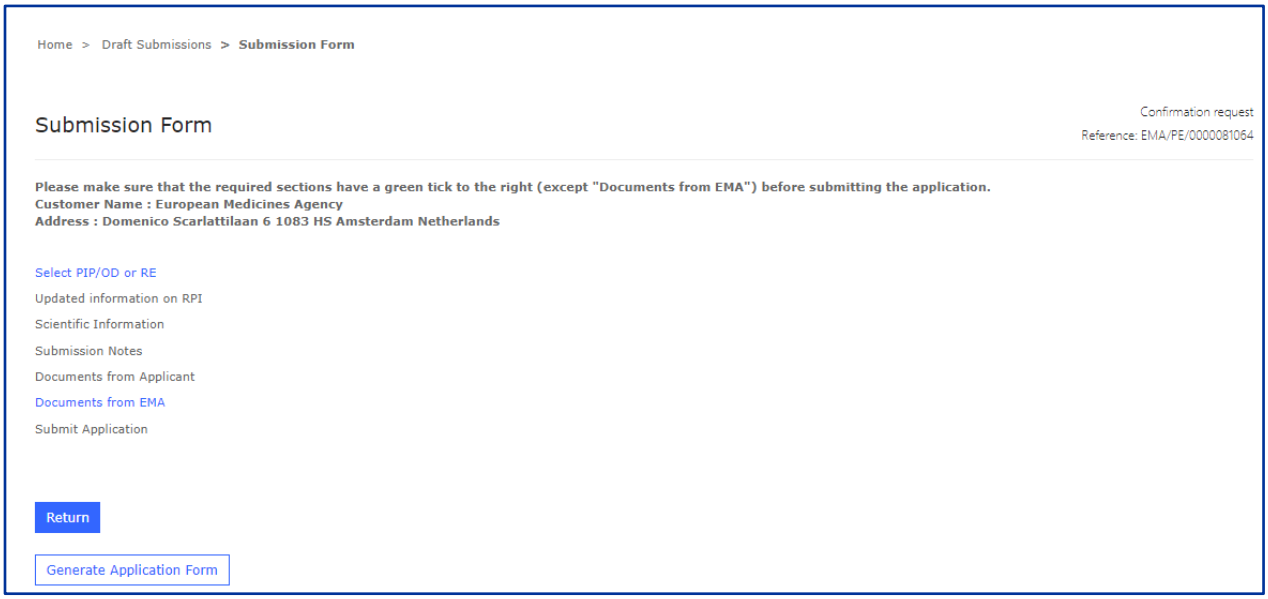


2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).

3. Follow the steps similarly as above in section 13.1. and note the following additional points:

   - Click on "**Select PIP/OD or RE**" and fill in the relevant information. This section (tab) must be completed before other sections (tabs) become available.

Figure 109. Submission form for confirmation requests

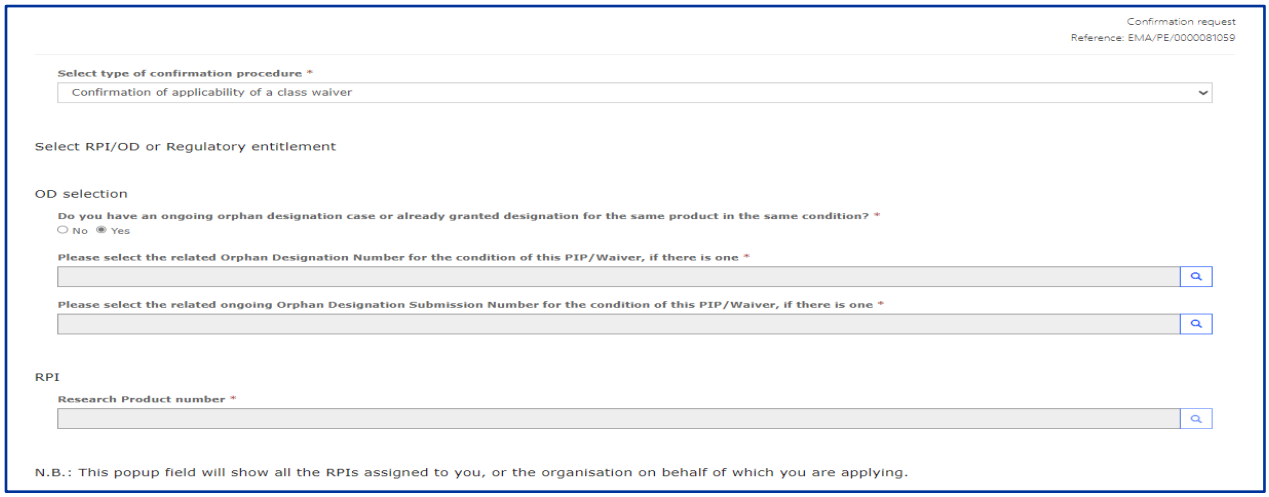


   - Select "Confirmation of applicability of a class waiver" OR "Confirmation of inclusion of an indication within a condition" as submission type, depending on your procedure.

Figure 110. Selection of the relevant confirmation request

- For "Confirmation of applicability of a class waiver", complete OD and / or RPI information.

Figure 111. Confirmation of applicability of a class waiver



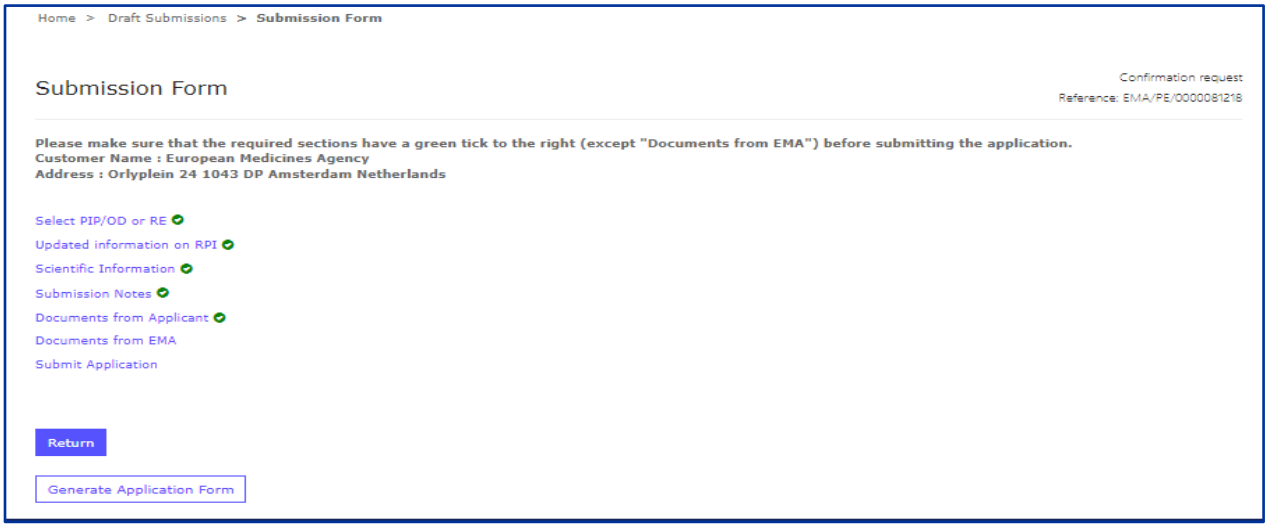
- For "**Confirmation of inclusion of an indication within a condition**", complete RE selection and RPI number will be auto-populated.

Figure 112. Confirmation of inclusion of an indication within a condition

4. Additional information can be added in **"Submission Notes"** section (tab) therefore a cover letter is not necessary. Do not leave it empty, if not used type "N/A".

5. Complete each required sections (tabs) ensuring that green tick to the right is displayed (except "Documents from EMA").
6. Click on "**Submit Application**" then complete the application similarly as in 13.1. (Figure 97).

Figure 113. Completed submission form for Confirmation requests

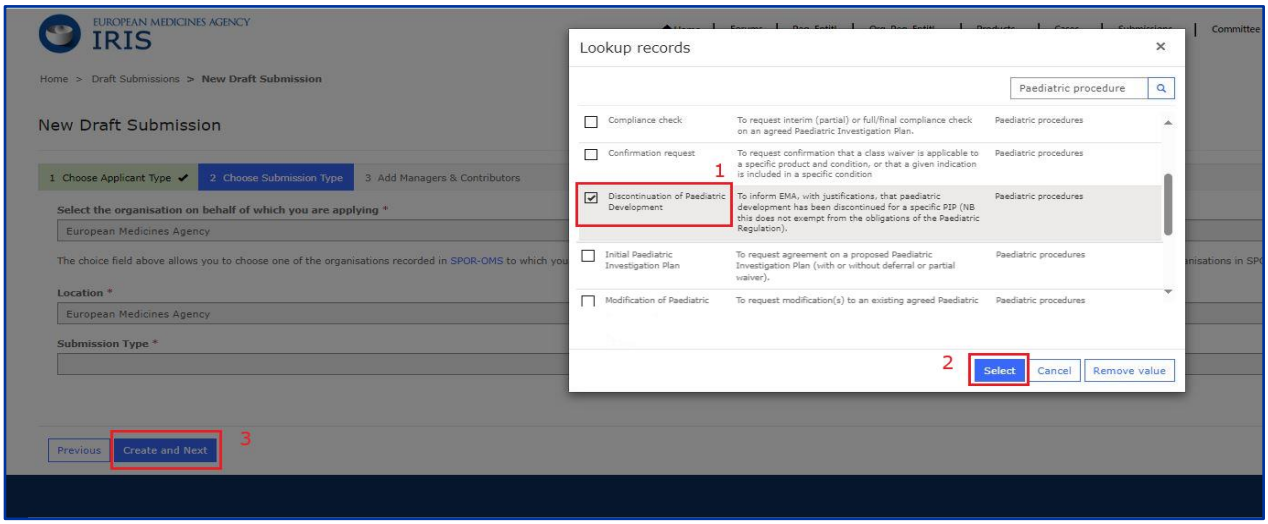


13.6.2. Create a submission for Discontinuation of paediatric development

In addition to the above Section 2.3. "Create a new submission":

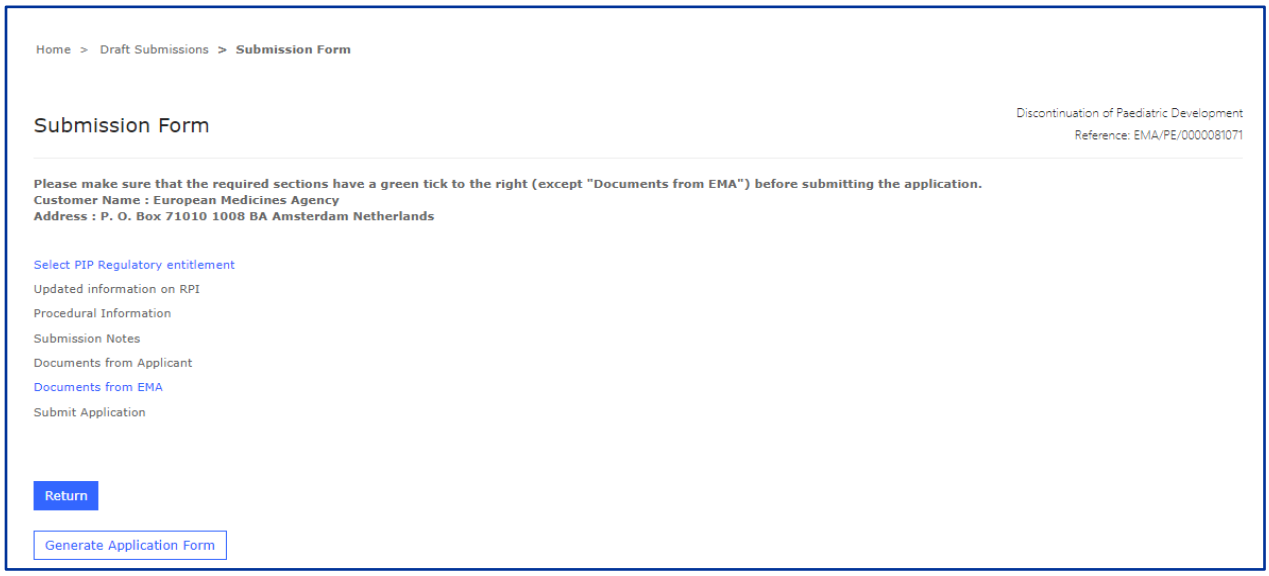
1. Type "Paediatric procedure" in Lookup records (search field) which will display all process types for paediatric procedures:
   - Chose "Discontinuation of paediatric development" as the submission type;
   - Click on "**Select**";
   - Click on "Create and Next".

Figure 114. Discontinuation of paediatric development submission



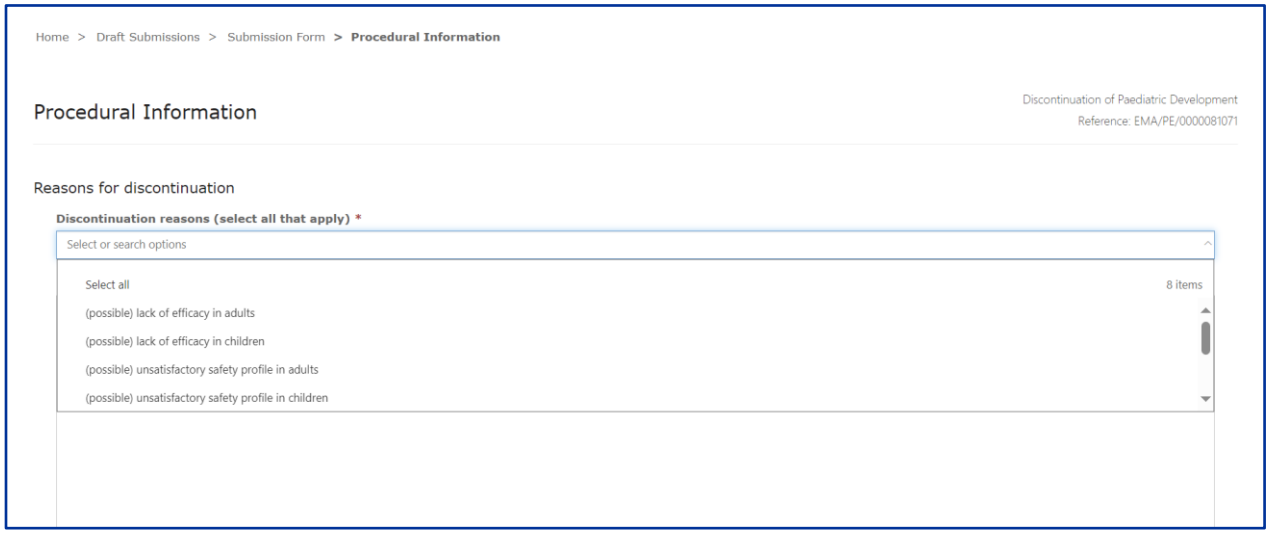
2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).
3. Follow the steps similarly as above in section 13.1. but note the following additional points:
    - Click on "**Select Paediatric Regulatory Entitlement**" and fill in the relevant information. This section (tab) must be completed before other sections (tabs) become available.

Figure 115. Submission form



- Select the reasons for this application in "**Procedural information**" section (tab), more than one selection is possible. Briefly describe the issues.

Figure 116. Discontinuation reasons



- Complete each required sections (tabs) ensuring that green tick to the right is displayed (except "Documents from EMA").
- Click on "**Submit Application**" then complete the application similarly as in 13.1. (Figure 97).

Figure 117. Completed submission form for Discontinuation of paediatric development

13.6.3. Transfer a paediatric regulatory entitlement

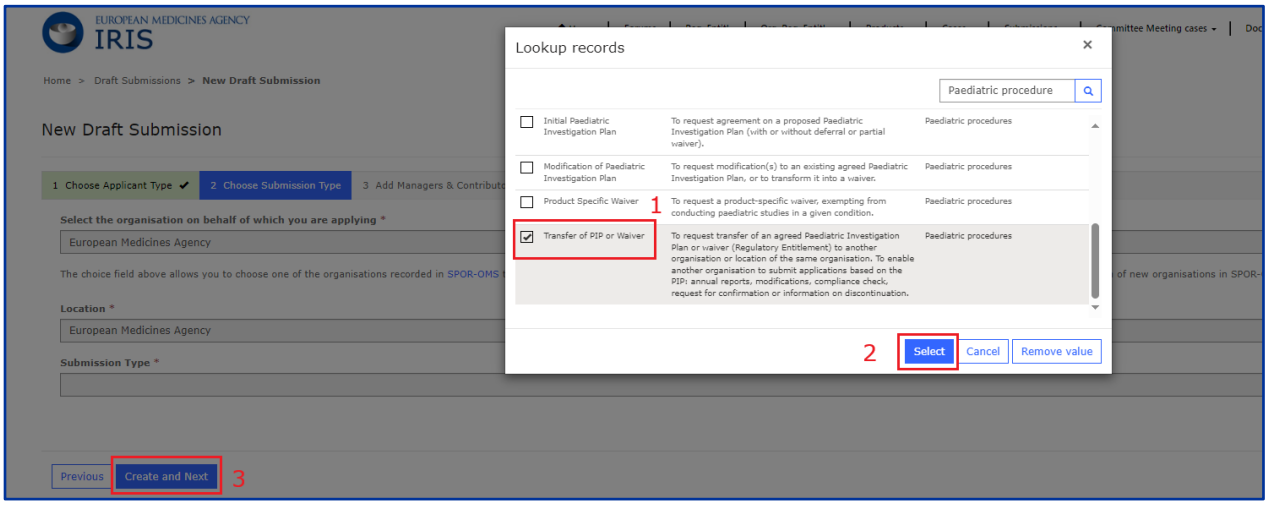
Owners of Paediatric Regulatory Entitlements (EMA decisions on Waivers, and agreed Paediatric Investigation Plans) are now able to transfer these regulatory entitlements to a different owner, or a different location of the same owner, via a self-service process in IRIS that is similar to the RPI transfer process.

Transferring a Paediatric Regulatory Entitlement is necessary when the applicant for a modification of an agreed PIP, a compliance check, an annual report on deferred measures, or a discontinuation report is different from the holder of the Paediatric Regulatory entitlement.

In addition to the above Section 2.3. “Create a new submission”:

1. Type “Paediatric procedure” in Lookup records (search field) which will display all process types for paediatric procedures:
    - Chose “**Transfer of PIP or Waiver**” as the submission type;
    - Click on “**Select**”;
    - Click on “Create and Next”.

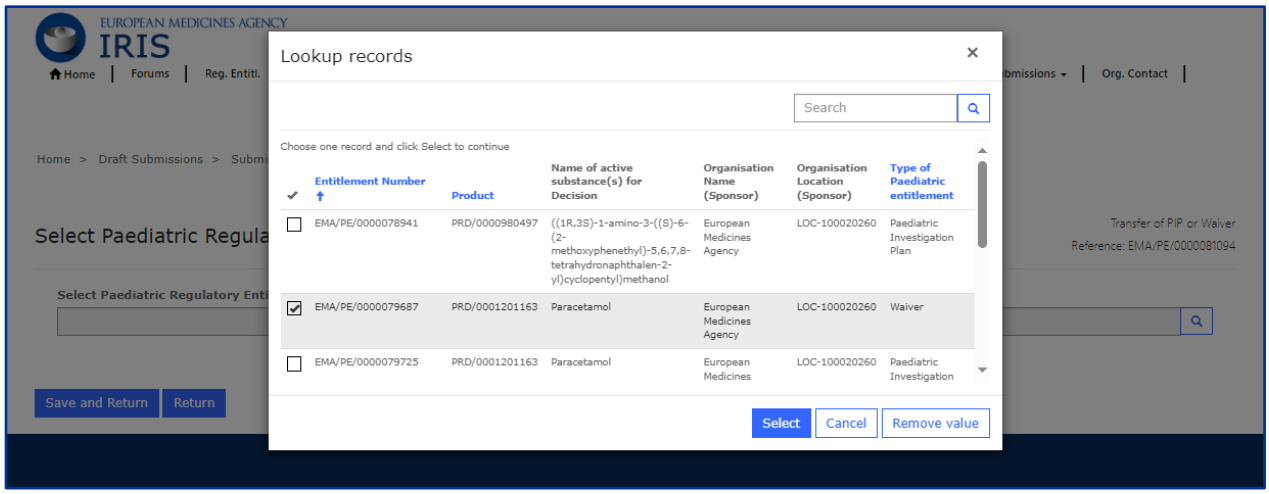
Figure 118. Lookup records



2. Refer to part 2.3 of this document for important notes and information on how to complete "**Add Managers & Contributors**" section then click "**Continue to Submission Form**" (Figure 4).
3. Follow the steps similarly as above in section 13.1. but note the following additional points:
    - Click on "Select Paediatric Regulatory Entitlement to be transferred" and chose the entitlement you wish to transfer.

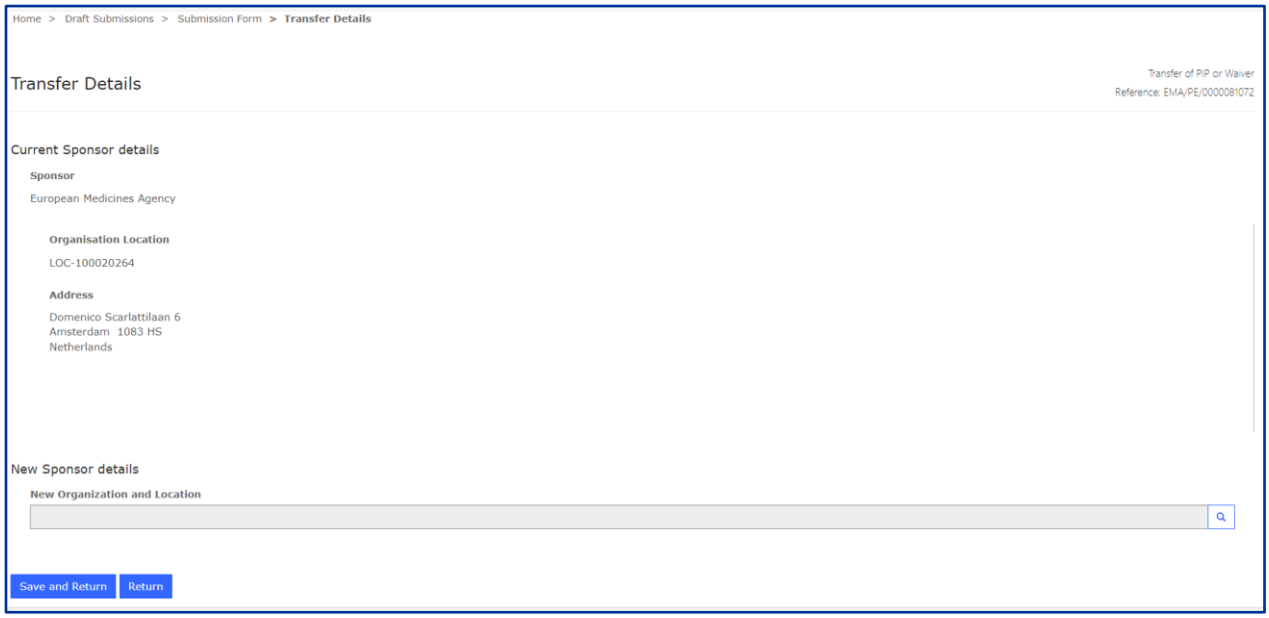
Figure 119. Submission form for Transfer of PIP or Waiver

Figure 120. Select paediatric regulatory entitlement for transfer



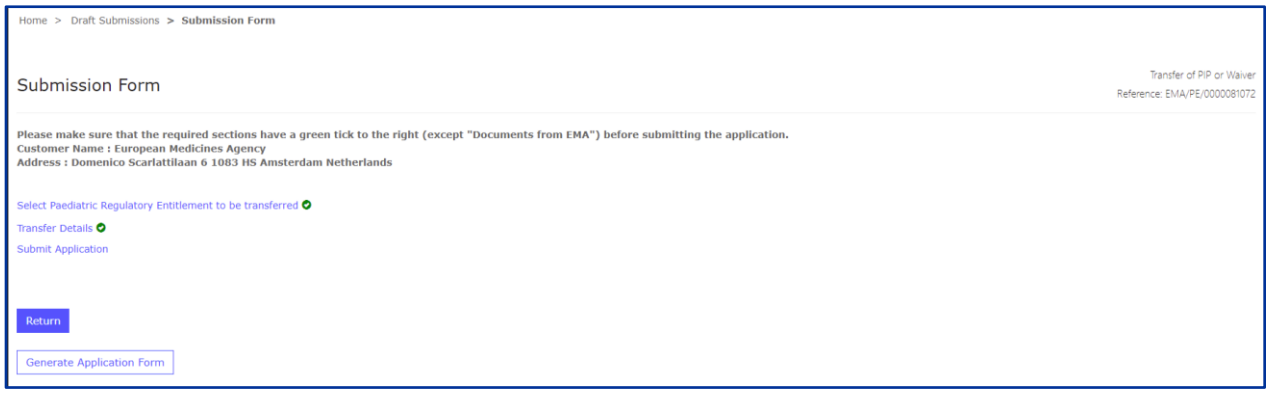
- Complete "**Transfer Details**" section (tab) by choosing new Organisation.

Figure 121. Transfer details



7. Complete each required sections (tabs) ensuring that green tick to the right is displayed (except "Documents from EMA")
8. Click on "**Submit Application**" then complete the application similarly as in 13.1. (Figure 97).

Figure 122. Submission form for Transfer of PIP or Waiver



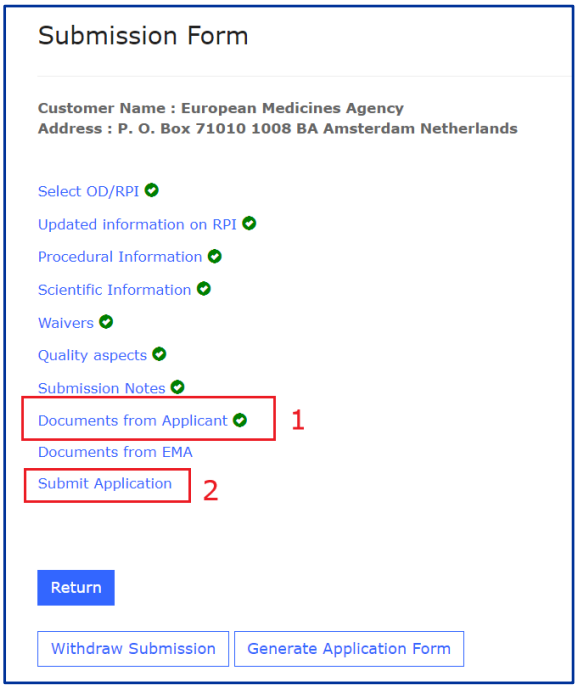
Note: to change / add a new submission contact refer to 13.6.6

13.6.4. Request for a re-examination of PDCO opinion

Applicants should notify their intention to request a re-examination replying to the latest IRIS communication (e.g. PDCO Opinion notification) **without changing the subject to ensure correct routing,** before submitting a detailed ground for re-examination of PDCO Opinion.

Once this notification is received, the applicant will be invited to submit their detailed grounds for the re-examination with a given deadline in IRIS, using "**Documents from Applicant"** section (tab).

Figure 123. Submission form



13.6.5. Submitting additional information during paediatric procedures

When the applicant is invited to provide additional information by a specific deadline, a notification is received either:

- Unlocked for upload - only new/revised documents can be uploaded in “Documents from Applicant” section. (Submit button is not enabled as not needed)

  And/or

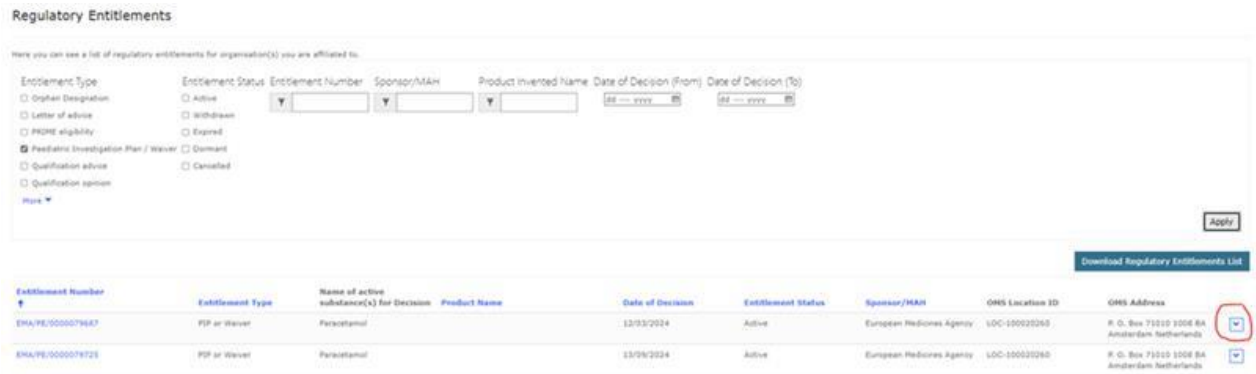
- Unlocked for edit - data can be amended (also possible to upload new documents, if needed). Click on Submit button is enabled and mandatory.

13.6.6. Changing contact person

- To change the contact person for draft or ongoing submissions please refer to the section 2.4 and 2.5.
- To change the contact person and / or the contact for public enquiries of a PIP for which a decision has been issued, update the regulatory entitlement also refer to the section 2.13.3.

Under Regulatory Entitlements, apply filter for Paediatric Investigation Plan / Waiver in Entitlement Type. A list of regulatory entitlements affiliated to your organisation will open. Find the related regulatory entitlement, click on the blue arrow and select “Contacts”.

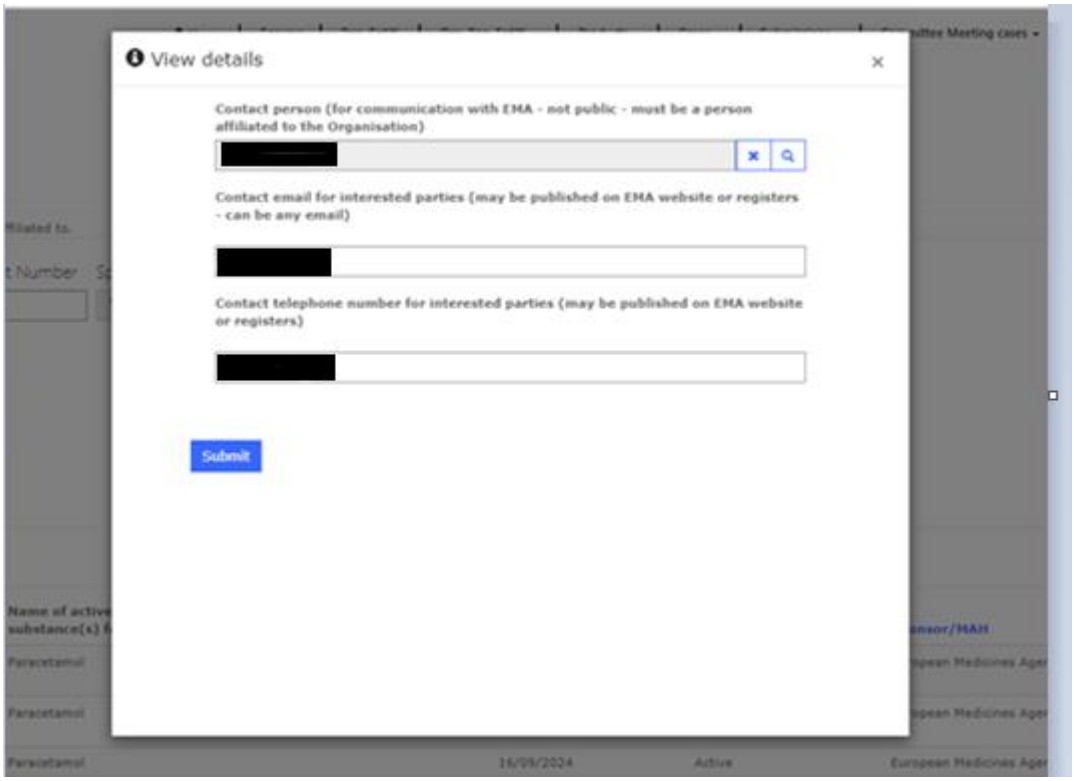
Figure 124. List of regulator entitlements by entitlement type



Then, proceed with the changes in the pop up window.

Note: “Contact email for interested parties” and “Contact telephone number for interested parties” will be published on the EMA website or registers. It is recommended to use a general e-mail address without personal information.

Figure 125. Pop up window for" Contact person", "Contact email for interested parties" and "Contact telephone number for interested parties"



Note: For transferring the agreed PIP to another company see Section 13.6.3

14. Annexes

14.1. Procedure number format in IRIS

Procedure number in IRIS format	Type of the procedure
EMA/**GE**/XXXXXXXXX	Change of name and/or address; Agenda item
EMA/**IN**/XXXXXXXXX	GCP, GMP, GVP, PhVP Inspections
EMA/**ITF**/XXXXXXXXXX	Innovation task force briefing meeting
EMA/**N**/XXXXXXXXXX	Article 61(3)
EMA/**OD**/XXXXXXXXXX	All **orphan** procedures: - application for orphan designation; - amendment of and existing orphan designation/condition

	only; - annual reports; - transfer of orphan designation; - maintenance of the orphan designation at the time of an orphan MAA; - removal of an orphan designation from the EC register; - 5y review market exclusivity period
EMA/**PAM**/XXXXXXXXXX	PAM - H & V
EMA/**PASS**/XXXXXXXXXX	PASS
EMA/**PE**/XXXXXXXXX	All paediatric procedures: • Initial paediatric investigation plan (PIP) including the response to PDCO RSI (if applicable) • Modification of paediatric investigation plan (modification of an agreed PIP) • Product-specific waiver • Compliance check • Annual report on paediatric deferred measures • Confirmation requests: – Confirmation of applicability of a class waiver, or – Confirmation of inclusion of an indication within a condition • Discontinuation of paediatric development.
EMA/**PMSS**/XXXXXXXXXX	Post marketing surveillance studies for V products
EMA/**PD**/XXXXXXXXX	Parallel distribution notifications for H&V products
EMA/**PR**/XXXXXXXXXX	All **PRIME** processes: PRIME eligibility procedure, PRIME meeting request, PRIME periodic update, Transfer or request a withdrawal of an existing PRIME regulatory entitlement
EMA/**PSUR**/XXXXXXXXXX	PSUR
EMA/**R**/XXXXXXXXXX	Renewal - 1 year; Renewal - 5 year

EMA/**REF**/XXXXXXXXXX	Referrals
EMA/**S**/XXXXXXXXXX	Annual reassessment - H & V
EMA/**SA**/XXXXXXXXXX	All **scientific advice** procedures H & V: Initial and follow up Scientific Advice, Initial and follow up Protocol Assistance, Initial and follow up Qualification
EMA/**T**/XXXXXXXXXX	Marketing Authorisation Transfer - H & V
EMA/**VR**/XXXXXXXXXX	Variation type IA, Variation type IA_IN, Variation type II (including worksharings), Variation type IB (including worksharings) - Human MP variations
EMA/**VRA**/XXXXXXXXXX	VRA-R; VRA-S; VRA-E; VRA-I – Veterinary MP variations
EMA/**X**/XXXXXXXXXX	Extension of Marketing Authorisation