How to provide consent for operational information sharing

Marketing Authorisation (MA) Applicants submitting relevant regulatory Marketing Authorisation Applications (MAAs) will be asked to provide consent to share operational information (https://www.gov.uk/government/publications/operational-information-sharing) with cross-UK health system partners during the MAA process on the MHRA's Human Medicines Portal (HM Portal).

This guide shows how consent will be requested via the HM Portal during the MAA submission process, and how MA applicants can provide consent to share operational information during the MAA process.

Consent to share operational information must be provided by, or on behalf of, an authorised signatory who is able to provide the assurances required on behalf of the proposed Marketing Authorisation Holder (MAH).

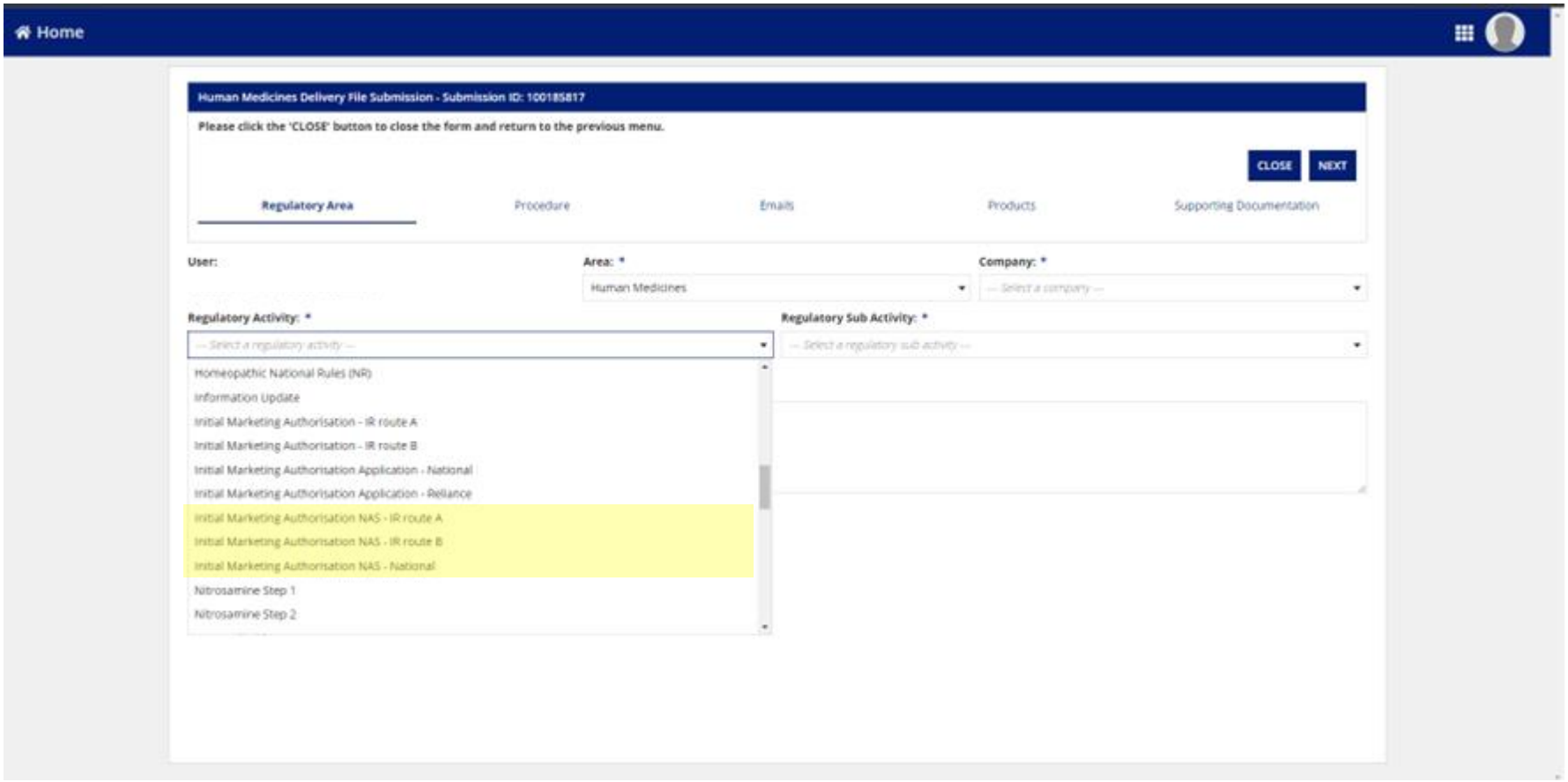
For any further queries please contact partnerships@mhra.gov.uk.

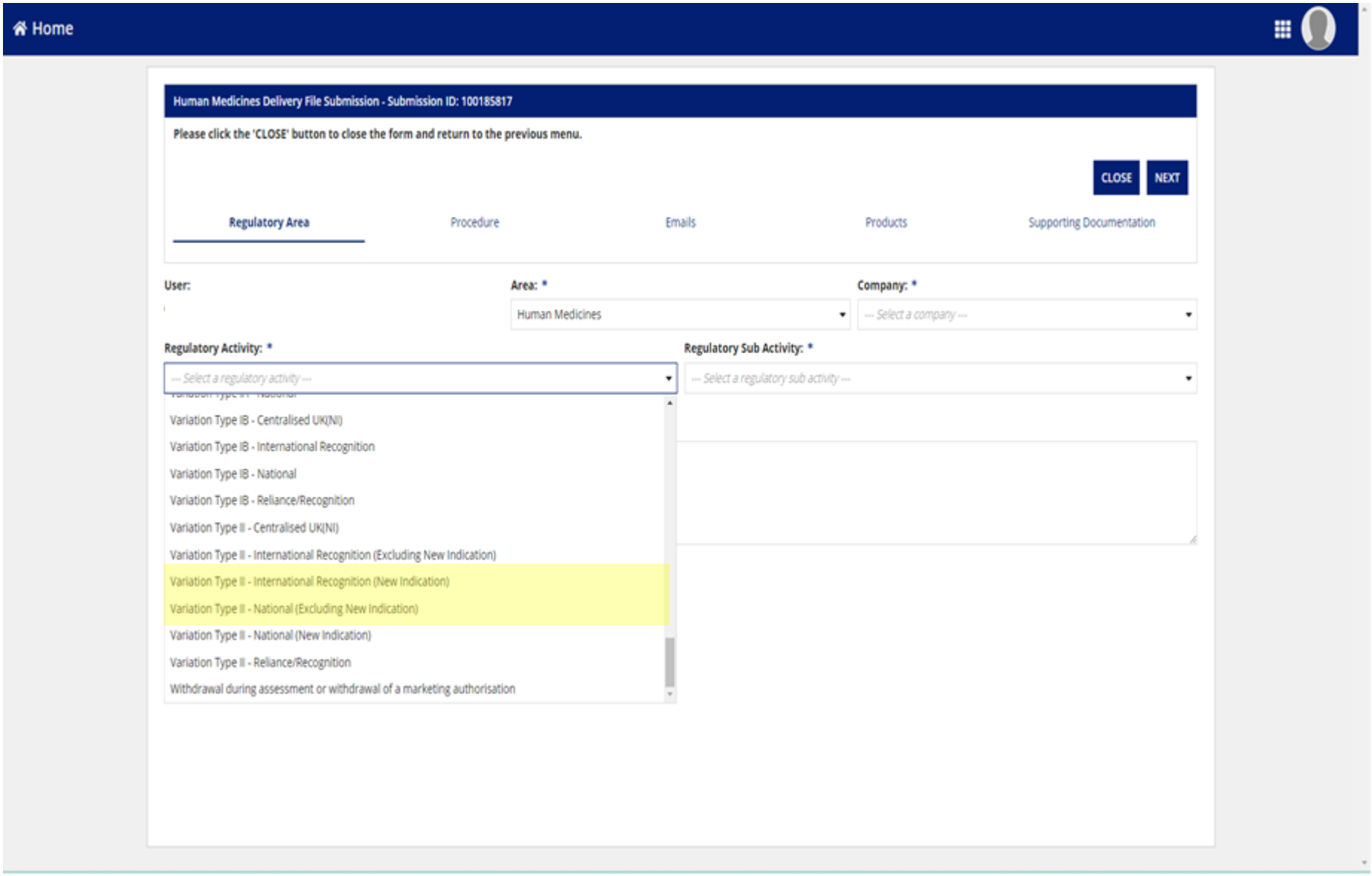
1. Please follow the relevant guidance that explains how to submit MAA for medicines via the HM Portal (available at “Webinars: information on how to make submissions to the MHRA - GOV.UK (www.gov.uk)” in https://www.gov.uk/guidance/webinars-information-on-how-to-make-submissions-to-the-mhra).

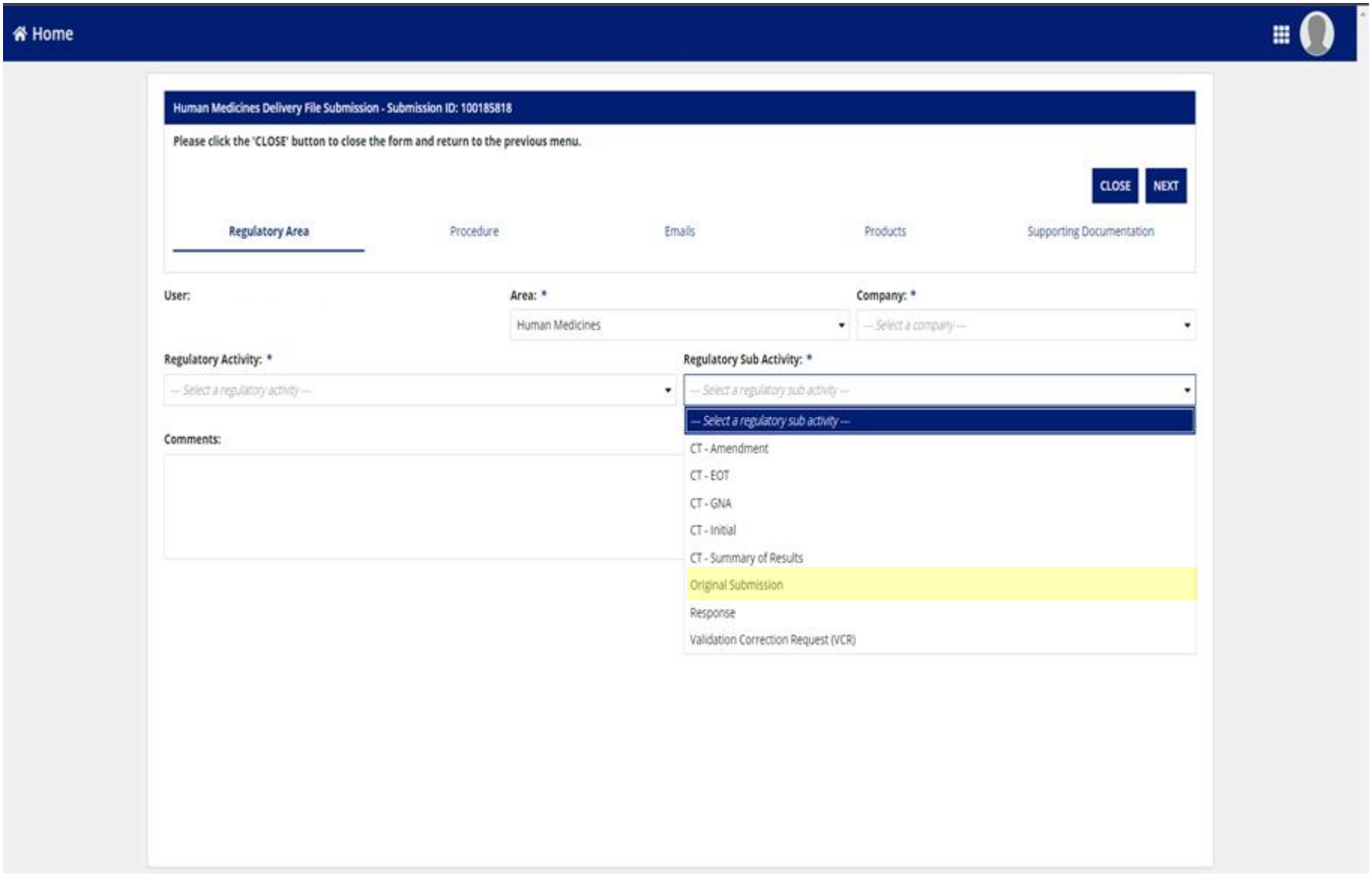
2. After selecting ‘Submit application’ in the appropriate page, the next screen of the application submission process captures the regulatory activity. Please proceed with your application filling in the ‘Regulatory Area’ section in accordance with the above guidance and as required for your application.

3. For your information, consent to share operational information will only be requested for ‘Human Medicines’ applications when one of the following options are selected from the drop-down list in ‘Regulatory Activity’ along with **‘Original Submission’** from the ‘Regulatory Sub Activity’ drop-down list during the MAA process.

- **‘Initial Marketing Authorisation NAS – National'**
- **‘Initial Marketing Authorisation NAS – IR Route A’**
- **‘Initial Marketing Authorisation NAS – IR Route B’**
- **‘Variation Type II – National (New Indication)’**
- **‘Variation Type II – International Recognition (New Indication)’**


Home
Human Medicines Delivery File Submission - Submission ID: 100185817
Please click the 'CLOSE' button to close the form and return to the previous menu.
CLOSE
NEXT
Regulatory Area
Procedure
Emails
Products
Supporting Documentation
User:
Area: *
Human Medicines
Company: *
— Select a company —
Regulatory Activity: *
— Select a regulatory activity —
Regulatory Sub Activity: *
— Select a regulatory sub activity —
Homeopathic National Rules (NR)
Information Update
Initial Marketing Authorisation - IR route A
Initial Marketing Authorisation - IR route B
Initial Marketing Authorisation Application - National
Initial Marketing Authorisation Application - Reliance
Initial Marketing Authorisation NAS - IR route A
Initial Marketing Authorisation NAS - IR route B
Initial Marketing Authorisation NAS - National
Nitrosamine Step 1
Nitrosamine Step 2


Home
Human Medicines Delivery File Submission - Submission ID: 100185817
Please click the 'CLOSE' button to close the form and return to the previous menu.
CLOSE
NEXT
Regulatory Area
Procedure
Emails
Products
Supporting Documentation
User:
Area: *
Human Medicines
Company: *
--- Select a company ---
Regulatory Activity: *
--- Select a regulatory activity ---
Regulatory Sub Activity: *
--- Select a regulatory sub activity ---
Variation Type IB - Centralised UK(NI)
Variation Type IB - International Recognition
Variation Type IB - National
Variation Type IB - Reliance/Recognition
Variation Type II - Centralised UK(NI)
Variation Type II - International Recognition (Excluding New Indication)
Variation Type II - International Recognition (New Indication)
Variation Type II - National (Excluding New Indication)
Variation Type II - National (New Indication)
Variation Type II - Reliance/Recognition
Withdrawal during assessment or withdrawal of a marketing authorisation


Home
Human Medicines Delivery File Submission - Submission ID: 100185818
Please click the 'CLOSE' button to close the form and return to the previous menu.
CLOSE
NEXT
Regulatory Area
Procedure
Emails
Products
Supporting Documentation
User:
Area: *
Human Medicines
Company: *
-- Select a company --
Regulatory Activity: *
-- Select a regulatory activity --
Regulatory Sub Activity: *
-- Select a regulatory sub activity --
-- Select a regulatory sub activity --
CT - Amendment
CT - EOT
CT - GNA
CT - Initial
CT - Summary of Results
Original Submission
Response
Validation Correction Request (VCR)
Comments:

4. In the next steps of the MAA process, proceed with your application filling in the ‘Procedure’, ‘Emails’, ‘Products’ and ‘Supporting Documents’ as required per your application.

5. Following confirmation of upload of documents as required per your application, for the relevant MAAs detailed in point 2, the proposed MAH will be asked to provide consent to share operational information to support timely patient access to medicines as shown in the screen below.

Human Medicines Delivery File Submission - Submission ID: 100185821

Please click the 'CLOSE' button to close the form and return to the previous menu.

Please click the 'SUBMIT' button to ensure that the submission has been submitted successfully.

CLOSE PREVIOUS

Regulatory Area | Procedure | Emails | Products | Supporting Documentation | **Submit**

Validate and Confirm: DRAFT

Validation	Tab Title	Status
✓	Regulatory Area	This form is complete.
✓	Procedure	This form is complete.
✓	Supporting Documentation	This form is complete.

Consent to share operational information to support timely patient access to medicines

Please read the following statement carefully:

I have read **MHRA's Operational Information Sharing Guidance** and give my consent on behalf of the proposed Marketing Authorisation Holder to MHRA to share specific operational information with health system partners, both as indicated in the guidance. *

Consent to share operational information

◯ Yes ◯ No

By completing the 'Yes' selection above, you confirm that:

- You consent to share operational information with MHRA's health system partners, as indicated in the statement above.
- You have read **MHRA's Operational Information Sharing Guidance**
- You are authorised by the proposed license holder to give this consent.

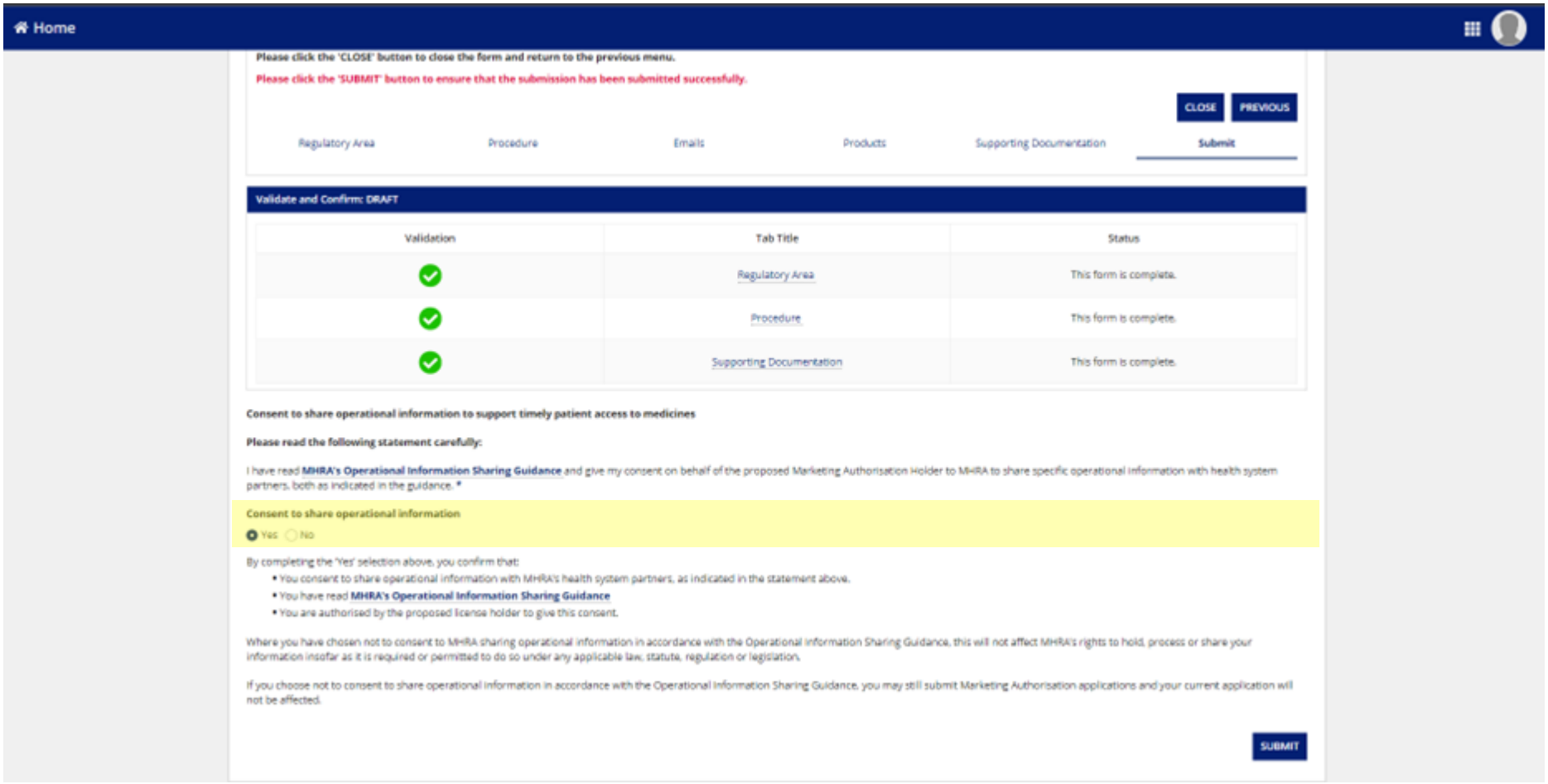
Where you have chosen not to consent to MHRA sharing operational information in accordance with the Operational Information Sharing Guidance, this will not affect MHRA's rights to hold, process or share your information insofar as it is required or permitted to do so under any applicable law, statute, regulation or legislation.

If you choose not to consent to share operational information in accordance with the Operational Information Sharing Guidance, you may still submit Marketing Authorisation applications and your current application will not be affected.

SUBMIT

6. Click **‘MHRA’s Operational Information Sharing Guidance’** to go to the gov.uk page (https://www.gov.uk/government/publications/operational-information-sharing) containing all the information about operational information sharing. Please read carefully the gov.uk page on Operational Information Sharing, and the Operational Information Sharing Guidance document on the linked page.

7. Please ensure again that you are the appropriate person to give consent for operational information sharing. At this stage, if you are the / on behalf of the authorised signatory who is able to provide the assurances required on behalf of the proposed MAA select **‘Yes’,** if you consent to operational information being shared with our health system partners as indicated in MHRA’s Operational Information Sharing Guidance (https://www.gov.uk/government/publications/operational-information-sharing).



8. Then click ‘Submit’ and continue your MAA as required per your application.

9. Once the application is submitted, and if you have selected **‘Yes’** to share operational information, consent will have been given to share operational information with our health system partners.