

## **User Reference Guide – MHRA E-cigarette Submissions 2022**

This is a step by step guide for users that wish to make submissions to notify E-cigarette products in Great Britain via MHRA Submissions.

The system has been developed to allow a submitted notification to be used as a base template for future notifications allowing notifiers to submit a range of products swiftly and efficiently.

### **[Section 1: How to make a Manual E-cigarette Submission](#)**

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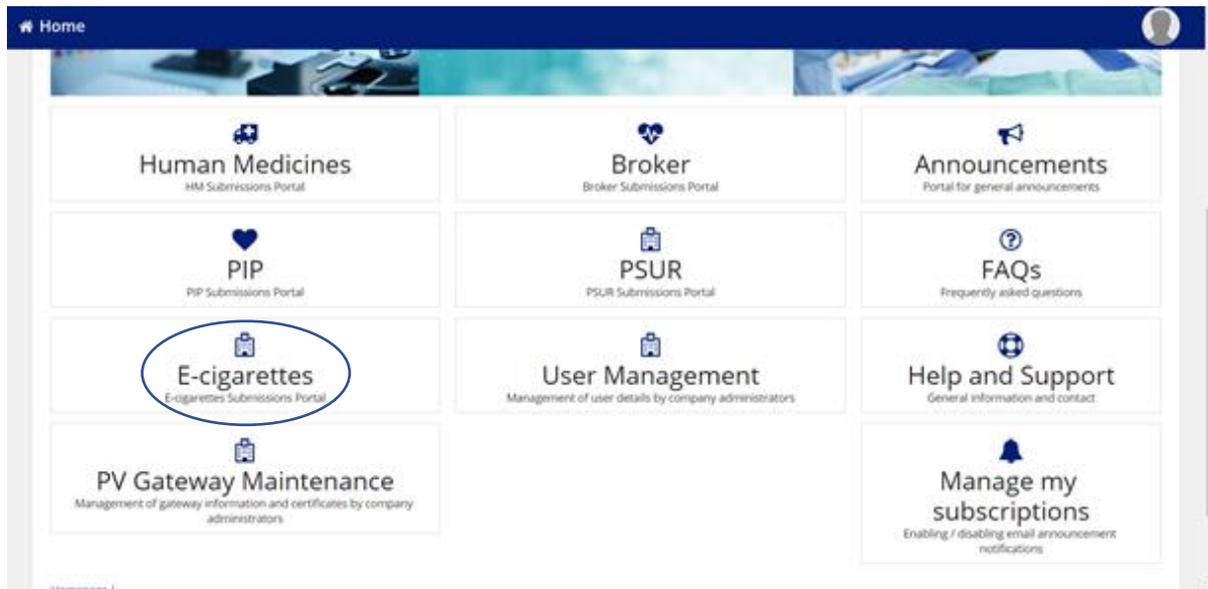
[1.10: Refer Document Guidance](#)

### **[Section 2: How to make Bulk XML E-cigarette Submissions](#)**

### **[Section 3: How to view previous submissions](#)**

### **[Section 4: How to submit updates](#)**

To make an E-cigarettes-related submission, navigate to the 'E-cigarettes' tile of the MHRA Submissions portal.

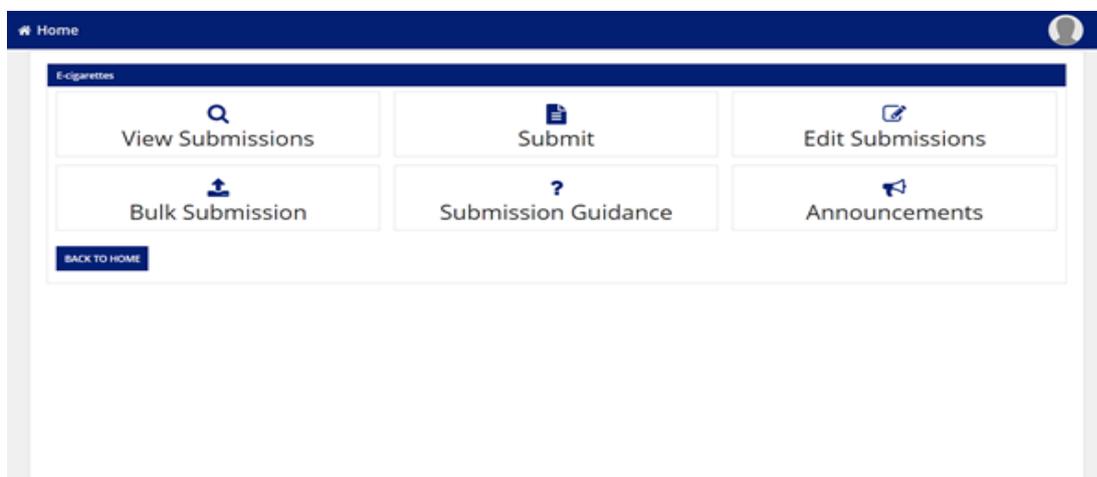


If a problem occurs whilst completing an E-cigarettes submission please return to the homepage and contact the support team under the 'Support tile'.

### **Section 1: How to make a Manual E-cigarette Submission**

*\*Note: You will be required to upload several documents during the process of your submission. For ease of access we have implemented a Refer Docs system which makes it easy for you to upload original documents then in future simply refer to those same documents instead of uploading them again. For guidance on document upload and refer docs please see 1.10: Refer Document Guidance [here](#)\**

To begin making a manual E-cigarette submission, select 'Submit' from the E-cigarettes tile homepage.

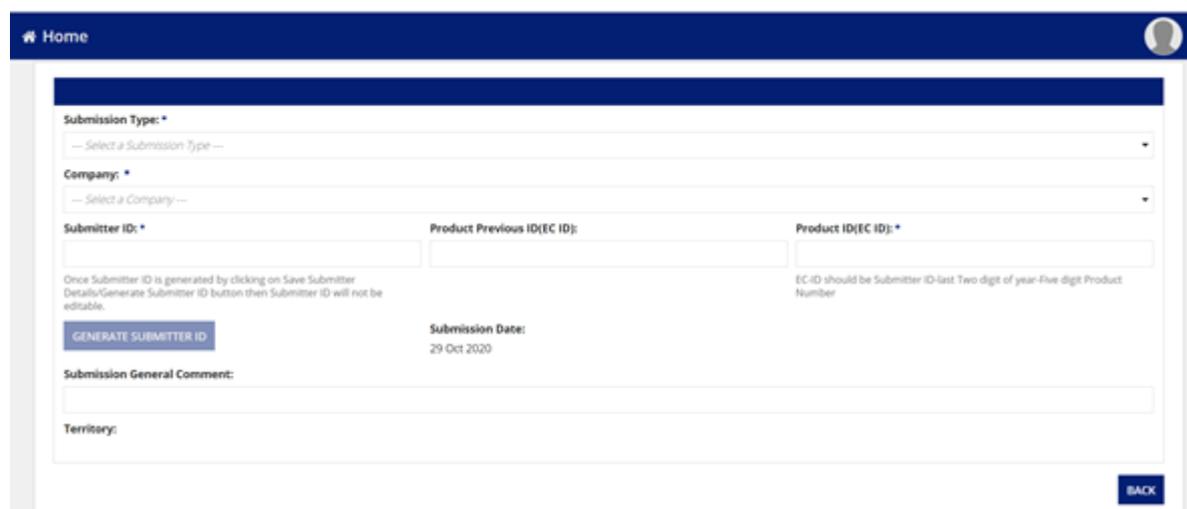


## 1.1: Submission Type/Submitter Info

Determine 'Submission Type' from the drop-down menu. Note: only one Type 1 submission is allowed for a submitter ID and product ID. This includes notifications that are submitted or saved as draft.

Select Company from drop-down menu.

Enter 'Submitter ID/Generate new Submitter ID/Submitter ID' will be auto-populated if previous submissions have been made.



The screenshot shows a web form titled 'Home' with a user profile icon. The form contains the following fields and elements:

- Submission Type:** A dropdown menu with the placeholder text '— Select a Submission Type —'.
- Company:** A dropdown menu with the placeholder text '— Select a Company —'.
- Submitter ID:** A text input field.
- Product Previous ID(EC ID):** A text input field.
- Product ID(EC ID):** A text input field.
- GENERATE SUBMITTER ID:** A blue button.
- Submission Date:** A text field showing '29 Oct 2020'.
- Submission General Comment:** A large text area.
- Territory:** A text input field.
- BACK:** A blue button in the bottom right corner.

Below the 'Submitter ID' field, there is a note: 'Once Submitter ID is generated by clicking on Save Submitter Details/Generate Submitter ID button then Submitter ID will not be editable.' Below the 'Product ID(EC ID)' field, there is a note: 'EC-ID should be Submitter ID-last Two digit of year-Five digit Product Number'.

Enter 'Product ID (EC-ID)' Format: Submitter ID-last two digits of the year (22)-five-digit product number (XXXXXX-XX-XXXXX).

Enter any general submission comments.

Select the 'Submitter Type' from the drop-down menu.

If 'Submitter SME' or 'Submitter has VAT', tick the relevant tick box (and enter submitter VAT).

Enter submitter details and tick whether 'Submitter Has Parent Company', 'Has Affiliate Company', or 'Submitter Appoints Enterer' and provide subsequent details. Then select **'Save Submitter Details'**.

After saving submitter details please proceed to the Product Details tab

*Note: 'Affiliate company' is your UK-based responsible person/entity as required under the regulations.*

Submitter Info

**Submitter Info**

[SAVE SUBMITTER DETAILS](#)

Submitter Type: \*

Submitter SME  Submitter has VAT

Country: \*

Address: \*

Phone: \* Email: \*

Submitter Has Parent Company  
 Submitter Has Affiliate Company  
 Submitter Appoints Enterer

[SAVE SUBMITTER DETAILS](#)

## 1.2: Product Details

Select 'Product Type' from the drop-down menu and if an Asterix appears alongside 'Weight E-liquid' and 'Volume E-liquid', fill in the fields.

Product Type: \*

Weight E-liquid:      
 Volume E-liquid:      
 CLP Classification:

'Market Research' or 'Study Summaries' can be uploaded if necessary (please see Refer Docs Guidance [here](#)). Then enter the 'CLP Classification' if an asterisk appears.

<p><b>Market Research File:</b></p> <p style="font-size: small; color: #666;">Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</p> <p style="text-align: center;"><a href="#" style="background-color: #003366; color: white; padding: 2px 5px;">REFER DOCS</a></p>	<p><b>Studies Summaries File:</b></p> <p style="font-size: small; color: #666;">Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</p> <p style="text-align: center;"><a href="#" style="background-color: #003366; color: white; padding: 2px 5px;">REFER DOCS</a></p>
---	---

**Market Research File:**

[UPLOAD](#)

[SAVE PRODUCT DETAILS](#)

Then select '**Save product details**'.

## 1.3: Product Presentation

Under the 'Product Presentation' tab, select 'Add' to enter details.

Enter 'Brand Name'.

Select 'UK' from the 'National Market' drop-down menu and provide any additional comments. If any 'Brand Subtype Name Exists', please tick the box and provide the 'Brand Subtype' name.

Brand Name: \*

National Market: \*

National Comment:

Brand Subtype Name Exist

Enter the e-cigarette launch date and withdrawal date (if indicated via 'e-cigarette withdrawal indication').

E-cigarette Launch Date: \*

E-cigarette Withdrawal Indication

Enter the 'Product Submitter Number', the 'UPC Number', the 'EAN Number', the 'GTIN Number', the 'SKU Number' and the 'Package Units' (where mandatory field is indicated with an Asterix). Where document upload is required please see 1.10: Refer Document Guidance [here](#).

Product Submitter Number: \*

Product UPC Number: \*

Product EAN Number: \*

Product GTIN Number: \*

Product SKU Number: \*

Package Units: \*

Unit Packet Picture File:

Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:

Product Sale Volume

Product Mode Of Sales

Product Sale Volume Year

Then provide any further details that are relevant to your submission.

*Note: Type 6 applications will need to include annual sales data as required under the regulations (please see 'Annual Reporting Guidance' via <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products> for further information).*

Then Select 'Add Presentation' before advancing. You can add further presentations by repeating Step 4 again.

*\*Note: Remember to click Save Presentation Details after entering details for each presentation added\**

Please proceed to the Ingredients tab

## 1.4: Ingredients

Under the 'Ingredients' tab, select 'Add', then enter the 'Name' then tick the 'CAS Exist' and enter CAS number. Complete all mandatory fields indicated with an Asterisk. To upload mandatory documents please see 1.10: Refer Document Guidance [here](#)

The screenshot shows a web form for adding an ingredient. The fields are as follows:

- Name:** \* (text input, value: test)
- Identification Refill Container Cartridge:** (text input)
- CAS Exist:**
- CAS Additional:** (table with 1 column and 1 row, value: No items available)
- ADD** (button)
- FEMA Number:** (text input)
- Additive Number:** (text input)
- FL Number:** (text input)
- Function:** (dropdown menu, value: -- Select the functions --)
- REACH Registration:** (dropdown menu, value: -- Select a REACH Registration --)
- EC Number:** (text input)
- Other Number:** (text input)
- Recipe Quantity:** (text input)
- Non Vaporised Status:** (dropdown menu, value: -- Select a Non Vaporised Status --)
- REACH Registration Number:** (text input)
- CLP Whether Classification**
- CLP Eye Damage/Irritation:** (dropdown menu, value: -- Select a CLP Eye damage/Irritation --)
- CLP Mutagen/Genotox:** (dropdown menu, value: -- Select a CLP Mutagen/Genotox --)
- CLP STOT:** (dropdown menu, value: -- Select a CLP STOT --)
- CLP STOT Description:** (text area)
- Tox Data:** (dropdown menu, value: -- Select a Tox Data --)
- Tox Emission**
- Tox CMR**
- Tox CardioPulmonary**
- Tox Addictive**
- Tox Other**
- ADD INGREDIENT** (button)

Where no toxicity studies or information can be found for any of the required aspects, the suitability of the ingredient for use in a product should be questioned. Producers are required to ensure their products can be considered safe and safety cannot be assumed in the absence of available data. Producers should carry out their own safety assessment where no information is available. Toxicology uploads with vague statements about lack of data/studies and no evidence of assessment will not be accepted, nor will placeholder documents.

TOX EMISSION

Tox CMR

Tox CardioPulmonary

Tox Addictive

Tox Other

**Tox CMR File: \***

UPLOAD Drop files here

REFER DOCS

**Tox CardioPulmonary File: \***

UPLOAD Drop files here

REFER DOCS

**Tox Addictive File: \***

UPLOAD Drop files here

REFER DOCS

**Tox Other File: \***

UPLOAD Drop files here

REFER DOCS

ADD INGREDIENT BACK

After selecting 'Add Ingredient', it will appear in the list as per below. Select 'Save Ingredient Details' before advancing. You can add further ingredients by repeating Section 1.4. An 'Ingredient' can be removed by selecting the red 'X'.

Ingredients

SAVE INGREDIENT DETAILS

test X

ADD

Please proceed to the Emission tab

## 1.5: Emission

Under the 'Emission' tab, select 'Add', then provide details for the mandatory fields as seen below and upload 'Method File' by selecting 'Upload'. For document upload please see 1.10: Refer Document Guidance [here](#)

Select 'Add Emission'. You can add further emissions by repeating Section 1.5. Select 'Save Emission Details' before advancing.

Methods File \*

Please use the REFER DOCS button to select a previously uploaded file or to upload a new document.

REFER DOCS

Name: \* Other Name:

--- Select a Value ---

CAS: \* IUPAC: \* Quantity: \* Emission Units: \*

ADD EMISSION BACK

Please proceed to the Design tab

## 1.6: Design

Under the 'Design' tab, enter the mandatory 'Description' in the free text field, upload the mandatory 'Production File' by selecting 'Upload' and tick the relevant box to indicate required declarations of conformity for your submission. Provide details for other fields where relevant to your submission (some of which will require mandatory document uploads depending on the product type). Please see 1.10: Refer Document Guidance [here](#)

<b>Nicotine Dose/Uptake File:*</b>
<i>Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</i>
<input type="button" value="REFER DOCS"/>

<b>Production File:*</b>
<i>Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</i>
<input type="button" value="REFER DOCS"/>

\*  
 Production Conformity

\*  
 Quality Safety

<b>Opening/Refill_File:</b>
<i>Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</i>
<input type="button" value="REFER DOCS"/>

\*  
 Child Tamper Proof

High Purity

\*  
 Non Risk

\*  
 Consistent Dosing

<b>Consistent Dosing Methods:</b>
<i>Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</i>
<input type="button" value="REFER DOCS"/>

<b>Leaflet File:</b>
<i>Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:</i>
<input type="button" value="REFER DOCS"/>

**Coil Resistance:**

<input type="text"/>
----------------------

Select 'Save Design Details' before advancing.

Please proceed to the Validate tab

## 1.7: Validate

Submitters intending to supply a product to the Northern Ireland market must upload their notification via the European Common Entry Gateway (EUCEG). Please see our [webpage](#) for guidance on EUCEG notifications.

Below this, sections that are completed will appear with a green tick (✔). Sections that are incomplete will appear with a red cross (✘). The 'Submit' button will not be made available until all sections have been completed.

Note: if you have not saved a tab, it will appear as incomplete.

Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.

Submitter Info   Product Details   Product Presentation   Ingredients   Emission   Design   **Validate**   Submission Status   Payment/Published Data

### Validate and Confirm

Submitters intending to supply a product to the Northern Ireland market must upload their notification via the European Common Entry Gate (EUCEG). Please see our webpage for guidance on EUCEG notifications. To receive the single fee discount for NI and GB submitters are required to notify products using matching ECIDs via EUCEG and MHRA portals.

Validation	Tab Title	Status
✔	<a href="#">Submitter Info</a>	This form is complete
✔	<a href="#">Product Details</a>	This form is complete
✔	<a href="#">Product Presentation</a>	This form is complete
✔	<a href="#">Ingredients</a>	This form is complete
✔	<a href="#">Emission</a>	This form is complete
✔	<a href="#">Design</a>	This form is complete

**SUBMIT**

Select 'Submit' to confirm submission.

## 1.8: (a) Single Payment

Review the information provided to ensure it is correct. If the information is incorrect, please return to the homepage and contact the support team under the 'Support tile'.

### Payment Details

**One Application**   £150.00  
**Reference**   E-cigarette Notification Fee - E551075-21-00000

---

**Total:**   **£150.00**

### Address Details

<b>Address Line 1</b> BRISTOL-MYERS SQUIBB HOUSE	<b>Address Line 2</b> UXBRIDGE BUSINESS PARK, SANDERSON ROAD
<b>Country</b> UNITED KINGDOM	<b>Post Code</b> UB8 1DH
	<b>Email Address</b> tester@moam.uk

ⓘ Please check the above information is correct and proceed with the payment

ⓘ Please Note that the Payments are Not Refundable.

**CANCEL**   **SUBMIT**

Confirm the information is correct by selecting 'Submit' at which point you will be able to download your invoice and proceed to payment.

## Submission Form

[Click Here to proceed for payment](#)

[Click Here to download the Proforma Invoice](#)

**Please note:** This invoice must be paid using the link provided above. Payments made using other MHRA payment services will not be processed and will significantly delay your submission.



## Enter card details

### Payment summary

E-cigarette Notification Fee

Total amount:

**£150.00**

### Card number

Accepted credit and debit card types



### Expiry date

For example, 10/23

Month      Year

 / 

### Name on card

### Card security code

The last 3 digits on the back of the card

### Billing address

This is the address associated with the card

Country or territory

Upon completion of a successful payment your submission will be passed to the assessment team for review.

# Confirm your payment

## Payment summary

E-cigarette Notification Fee

Total amount:

**£150.00**

Card number ●●●●●●●●●●1111

Expiry date 10/23

Name on card Lambs Pou

Billing address

Confirmation email lambs@moam.uk

[Confirm payment](#)

If you wish to pay at a later date the submission will appear with 'Pending Payment' status in both the 'View' and 'Edit Submission' tiles.

## 1.8: (b) Bulk Payment

To make a single payment for multiple notifications, return to the home screen and select the "Edit submissions" tile. Then check the tick box "Pay Pending Notifications" (see Figure 1) and select the required notifications in the left column then click "Proceed to Payment" button at the bottom of the page (see Figure 2 below)

Home

CLOSE

E-cigarette SEARCH

Product ID(EC-ID): E454554 Product Type: --- Select a Value --- Submission Type: --- Select a Value ---

Submission Comment: Previous Product ID: Status: PENDING PAYMENT

Submission Date: 21/01/2022 Modified Date: 21/02/2022 Pay Pending Notifications:

SEARCH

<input type="checkbox"/>	Case ID	Product ID(EC-ID)	Previous Product ID	Submission Date	Modified Date	Submission Type	Product Type	Submission Comment	Status
<input type="checkbox"/>	100174159	E454554-22-00005		21/02/2022	21/02/2022	Notification of information on a new product (new EC-ID)- TYPE 1	Electronic cigarette- Disposable		PENDING PAYMENT
<input type="checkbox"/>	100174069	E454554-22-00004		17/02/2022	17/02/2022	Notification of information on a new product (new EC-ID)- TYPE 1	Electronic cigarette- Disposable		PENDING PAYMENT

Figure 1 - Tick "Pay Pending Notifications"

Home

CONFIRM SUBMISSIONS FOR PAYMENT

PRODUCT ID	SUBMITTED DATE	REFERENCE NUMBER	AMOUNT
E454554-22-00004	17/02/2022	100174069	£150.00
E454554-22-00005	21/02/2022	100174159	£150.00
<b>TOTAL AMOUNT:</b>			<b>£300.00</b>

CANCEL PROCEED TO PAYMENT

Figure 2 – Select notifications then proceed to payment

On the next page, check all the details are correct and click the "Submit" button (See Figure 3)

Home

One Application £150.00  
Reference E-cigarette Notification Fee - E454554-100002662-2

PRODUCT/EC ID	AMOUNT
E454554-22-00004	£150.00
E454554-22-00005	£150.00

**TOTAL AMOUNT: £300.00**

**Address Details**

**Address Line 1**  
4250 14TH AVENUE

**Country**  
CANADA

**Address Line 2**

**Post Code**  
L3R 0J3

**Email Address**  
lamb@moam.uk

**Please check the above information is correct and proceed with the payment**

**Please Note that the Payments are Not Refundable.**

CANCEL SUBMIT

Figure 3 – Verify details before selecting “Submit”

On the following page you will be given the option to download the Proforma Invoice (PDF) before making your payment (See Figure 4)

Home

**Submission Form**

[Click Here to proceed for payment](#)

[Click Here to download the Proforma Invoice](#)

**Please note:** This invoice must be paid using the link provided above. Payments made using other MHRA payment services will not be processed and will significantly delay your submission.

Figure 4 - Download Proforma Invoice

On the next page, enter your payment details and select the “Confirm Payment” button as displayed in the below screen shot (See Figure 5)

## Confirm your payment

**Payment summary**  
E-cigarette Notification Fee  
Total amount:  
**£300.00**

Card number	●●●●●●●●●●1111
Expiry date	10/24
Name on card	Lambs Pou
Billing address	4250 14TH AVENUE, MARKHAM ON, L3R 0J3, Canada
Confirmation email	lambs@moam.uk

[Confirm payment](#)

[Cancel payment](#)

Figure 5 – Confirm payment details then pay

On the next page you will receive confirmation your payment completed successfully. Please click “Submit Applications” button to submit your notifications for assessment (See Figure 6)

Home

Payment complete

Your payment completed successfully. Please submit your applications

PRODUCT ID	REFERENCE NUMBER
E454554-22-00004	100174069
E454554-22-00005	100174159

[SUBMIT APPLICATIONS](#)

Figure 6 – Submit Applications

Once your notifications have been successfully submitted and paid, they will be listed with your other notifications with a status of “Active” (See Figure 7) You will also receive a confirmation email and invoice.

Home

CLOSE

E-cigarette SEARCH

Product ID(EC-ID): E454554 Product Type: --- Select a Value --- Submission Type: --- Select a Value ---

Submission Comment: Previous Product ID: Status: --- Select status ---

Submission Date: 21/01/2022 Modified Date: 21/02/2022

SEARCH

Case ID	Product ID(EC-ID)	Previous Product ID	Submission Date	Modified Date	Submission Type	Product Type	Submission Comment	Status
100174159	E454554-22-00005		21/02/2022	21/02/2022	Notification of information on a new product (new EC-ID)- TYPE 1	Electronic cigarette- Disposable		ACTIVE
100174069	E454554-22-00004		21/02/2022	21/02/2022	Notification of information on a new product (new EC-ID)- TYPE 1	Electronic cigarette- Disposable		ACTIVE

Figure 7 - Active Notification Status

The 'Payment/Published Data' tab will summarise the current status of the payment, the data that will be published upon completion of a successful notification and the current publication status of the product (see figure 8)

BACK

Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.

Submitter Info Product Details Product Presentation Ingredients Emission Design Submission ID **Payment/Published Data**

Payment Details

Payment Status

- Status : FAILURE
- Amount Paid : £150.00
- Description : E-cigarette Notification Fee
- Reference : E551075-21-00000
- Card Holder Name : Test Testerson
- Billing Address : BRISTOL-MYERS SQUIBB HOUSE,UXBRIDGE BUSINESS PARK, SANDERSON ROAD,UXBRIDGE,GB,UB8 1DH

PROCEED TO PAYMENT

Published Data

Published Data is only visible for Published or Unpublished Submissions.

Figure 8 - Payment Status

*\*Note: A product submission (an "Active" product status) is not cleared for supply until it has been assessed by the E-cigarette team and published on the [MHRA publication page](#) . Supply of a product prior to publication is an offence.\**

## Submission ID

You will be able to view your MHRA submission number at any time after selecting 'Submit' in the 'Submission ID' tab (Please see figure 9)



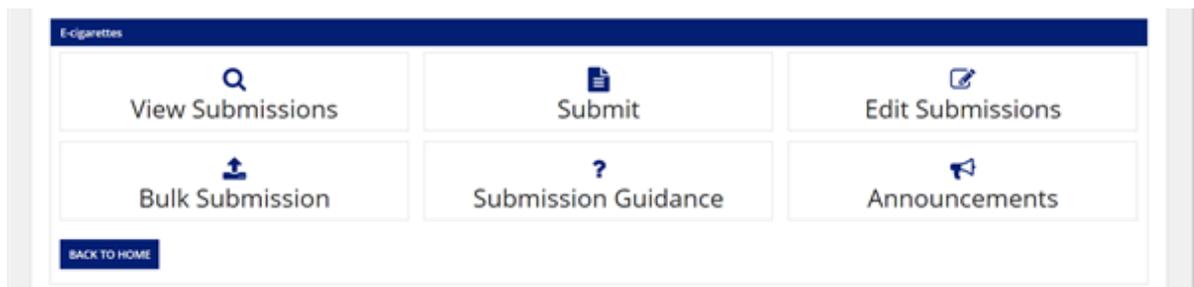
Figure 9 - Submission number

Click close to return to the E-cigarettes homepage.

## 1.9: Notifying further products

The system has been developed to allow a submitted notification to be used as a base template for future notifications allowing notifiers to submit a range of products swiftly and efficiently.

From the homepage, select edit submissions



Find the notification you have just submitted or want to duplicate and open by clicking the Case ID. The notification should load prepopulated with submission details.

A screenshot of a submission form. It includes fields for "Submission Type:" (with a dropdown menu), "Company:" (with a dropdown menu), "Submitter ID:" (with a "GENERATE SUBMITTER ID" button), and "Product ID/EC ID:" (with a text input field and a note: "EC-ID should be Submitter ID-last Two digit of year-Five digit Product Number"). There is also a "Start Date:" field showing "13 Mar 2019" and a "Submission General Comment:" field.

Select Submission Type 1 and enter your new product ECID by editing what has been prepopulated. Click Save Submitter Details, this will return you to the homepage (please wait 5 minutes for the data to refresh). Go back to Edit Submissions and find the new Product ECID which you have just created.

*\*Note: This notification will be prepopulated with information from the original notification, as such you will need to manually make amendments in this notification which will differentiate it from the original e.g. nicotine strength, capacity\**

## 1.10: Refer Document Guidance

With the updated changes now implemented, when uploading attachments, you will be asked if the intended document has already been uploaded.

The screenshot shows a web interface with a dark blue header containing a home icon and the text 'Home'. On the right side of the header is a grid icon and a user profile icon. The main content area is white and contains the following elements:

- CLP STOT:** A dropdown menu with the text '--- Select a CLP STOT ---'.
- Tox Data: \*** A dropdown menu with the text 'Toxicological data is available but not new.'
- A list of checkboxes for toxicity categories:
  - Tox Emission
  - Tox CMR
  - Tox CardioPulmonary
  - Tox Addictive
  - Tox Other
- Is the document present already in Prior Ingredients? \*** with radio buttons for  YES and  NO.
- At the bottom, two buttons: 'ADD INGREDIENT' and 'BACK'.

If it is 1<sup>st</sup> time you are uploading this document – select “No” and you will be directed to the below screen where you will be able to upload a document from your computer using the “Upload” button.

The screenshot shows a web interface with a dark blue header containing a home icon and the text 'Home'. On the right side of the header is a grid icon and a user profile icon. The main content area is white and contains the following elements:

- A message: 'Please use the REFER DOCS button to select a previously uploaded file or to upload a new document.'
- A button labeled 'REFER DOCS'.
- List of Documents** section with search filters:
  - Case ID: [text input]
  - EC-ID/GB-ID: [text input]
  - Document Name: [text input]
  - Reference Type: [dropdown menu: --- Select a Value ---]
  - Document Type: [dropdown menu: --- Select a Value ---]
  - From Upload Date: 17/01/2022 [calendar icon]
  - To Upload Date: 17/02/2022 [calendar icon]
- A 'CLOSE' button.
- A table with columns: EC-ID/GB-ID, Document, Case ID, Reference Type, Document Type, and Uploaded Date. The table is currently empty with the text 'No Data Available' centered below it.
- Unit Packet Picture File:** section with an 'UPLOAD' button and a text input field with a placeholder 'Drop files here'.
- At the bottom, three text input fields labeled 'Product Sale Volume', 'Product Mode Of Sales', and 'Product Sale Volume Year', with a 'REFER DOCS' button and a '+' icon.

Home

Is the document present already in Prior Ingredients? \*

YES

NO

Tox Other File

Please use the REFER DOCS button to select a previously uploaded file or to upload a new document:

REFER DOCS

List of Documents

Case ID:  EC-ID/GB-ID:  Document Name:

Reference Type:  Document Type:

From Upload Date: 17/01/2022 To Upload Date: 17/02/2022

CLOSE

<input type="checkbox"/>	EC-ID/GB-ID	Document	Case ID	Reference Type	Document Type	Uploaded Date
<input type="checkbox"/>	E454554-22-00004	TEST DOC 2.pdf	100174069	Ingredient	Tox Other Doc	17/02/2022 21:50 GMT

Tox Other File: \*

UPLOAD

However, if you have previously uploaded this document select “Yes”

You will then be given the option to select which from a list of previously uploaded documents.

Home

Tox Data: \*

Toxicological data is available but not new.

Tox Emission

Tox CMR

Tox CardioPulmonary

Tox Addictive

Tox Other

Is the document present already in Prior Ingredients? \*

YES

NO

Select The Ingredient which holds the Document \*

Nicotine

ADD INGREDIENT BACK

Home

Note: Total number of EC-ids cannot be more than 50

Product Combination:

Methods File:

Is the document present already in Prior Emissions? \*

YES  
 NO

Select The Emission which holds the Document \*

Acrolein

Name: \* Other Name:

Acetaldehyde

CAS: \* IUPAC: Quantity: \* Emission Units: \*

2-22-2

1 2

ADD EMISSION BACK

Once you have selected the required document click “Add Emission” and continue with your submission as normal.

## Section 2: How to make Bulk XML E-cigarette Submission

*\*Note: The MHRA Portal will only recognise the ‘Export’ file of the XML which is a condensed file type. This will not work with the ‘Data’ file which is the file used to make changes to the product notification in the EU-CEG XML Creator\**

EU-CEG XML Creator

EU-CEG XML Creator

Welcome Submitters Tobacco Product Submitters E-Cigarette Submitters Attachments

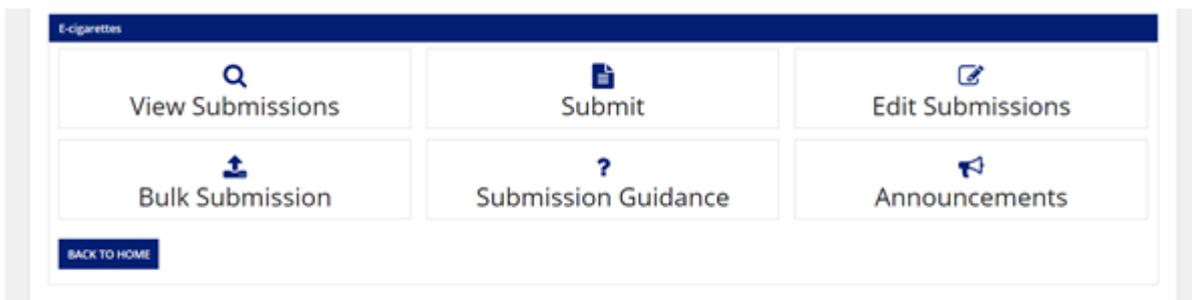
LIST OF E-CIGARETTES

Filter list of E-Cigarette Product Submissions

Add a new e-cigarette Export submission list

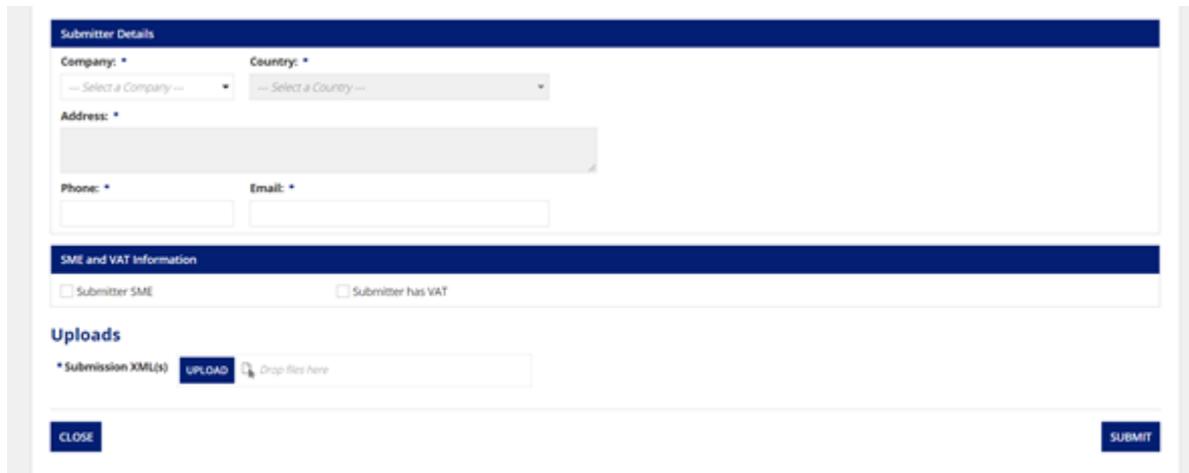
N°	Product Id	Product Type	Previous Product Id	Product National Market	Submission Type	Submission Comment	Status	Modified D...	Actions
1		Disposable		GB	1 - New product		CREATED	2021/02/12	<a href="#">Edit</a> <a href="#">Export</a>

To begin making an E-cigarette submission, select ‘Bulk Submission’ from the E-cigarette tile homepage.



## Step 2.1: Submitter Details

Select Company and Country from drop-down menu.  
Enter phone number and email address



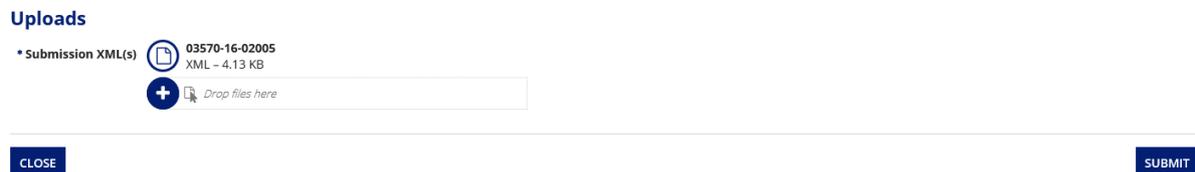
The screenshot shows a web form titled "Submitter Details". It contains several input fields: "Company:" and "Country:" are dropdown menus with "Select a Company" and "Select a Country" respectively. Below them is an "Address:" text input field. Further down are "Phone:" and "Email:" text input fields. A section titled "SME and VAT Information" contains two checkboxes: "Submitter SME" and "Submitter has VAT". Below this is an "Uploads" section with a "Submission XML(s)" label, an "UPLOAD" button, and a "Drop files here" area. At the bottom of the form are "CLOSE" and "SUBMIT" buttons.

## Step 2.2: Submitter Info

If 'Submitter SME' or 'Submitter has VAT'; tick the relevant tick box (and enter submitter VAT).

## Step 2.3: Uploading XML files

Click upload tab and select XML documents from your files.



The screenshot shows the "Uploads" section of the form. It features a "Submission XML(s)" label, a file icon, and the text "03570-16-02005 XML - 4.13 KB". Below this is a plus sign icon and a "Drop files here" area. At the bottom of the section are "CLOSE" and "SUBMIT" buttons.

## Step 2.4: Submitting XML

Once XML submissions are present under "uploads" you can select submit.  
After submitting you will see a Bulk Submission Confirmation message and Email confirming the submission is available as a draft. Select "close" to return to menu.

## Step 2.5: Review of draft submissions

Select "edit submission" to view your recent draft submission.

*\*Note: edit only shows recent submissions. "View" displays all historic submissions\**

**CLOSE**

**E-cigarette SEARCH**

Product ID(EC-ID):  Product Type:  Submission Type:

Submission Comment:  Previous Product ID:  Status:

Submission Date:  Modified Date:  Territory:

**SEARCH**

Case ID	Product ID(EC-ID)	Previous Product ID	Submission Date	Modified Date	Submission Type	Product Type	Submission Comment	Status	Territory
100114783	01052-16-00160		29/10/2020	29/10/2020	Notification of information on a new product (new EC-ID)- TYPE 1			Draft	Great Britain (GB)

Select case ID to view draft. Select validate to review the success of your upload. Under the 'Validate' tab, sections that are completed will appear with a green tick (✓). Sections that are incomplete will appear with a red cross (✗). The 'Submit' button will not be made available until all sections have been completed. You will be required to manually add documents and CLP Stot Description to required fields.

*\*Note: if you have not saved a tab, it will appear as incomplete. Select 'Submit' to confirm submission\**

Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.

Submitter Info   Product Details   Product Presentation   Ingredients   Emission   Design   **Validate**   Submission Status   Payment/Published Data

**Validate and Confirm**

Submitters intending to supply a product to the Northern Ireland market must upload their notification via the European Common Entry Gate (EUCEG). Please see our webpage for guidance on EUCEG notifications. To receive the single fee discount for NI and GB submitters are required to notify products using matching ECIDs via EUCEG and MHRA portals.

Validation	Tab Title	Status
✓	Submitter Info	This form is complete
✓	Product Details	This form is complete
✗	Product Presentation	Please fill all mandatory fields and Click on Save button
✗	Ingredients	Please fill all mandatory fields and Click on Save button
✗	Emission	Please fill all mandatory fields and Click on Save button
✗	Design	Please fill all mandatory fields and Click on Save button

**SUBMIT**

## Step 2.6: Activation of Draft Submission

After submitting the draft submission make note of the submission number then click close to return to the user menu.

Click View Submissions where you will be able to see your notification with an "Active" status.

**Submission Status**

Your submission has been Submitted. This is the Reference Number:  
**Submission Number:** 100044374

**CLOSE**

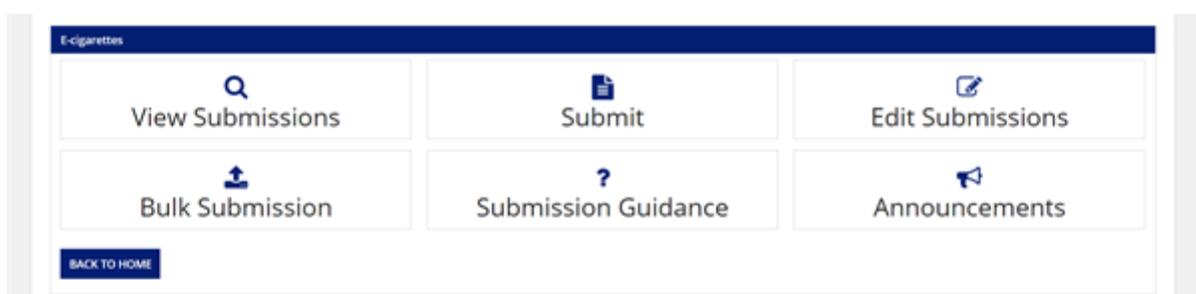
## Step 2.7: Payment of Draft Submission

To make payments for your submission please see Section 1.8 a/b

***\*Activation does not confirm assessment and publication of ECIDs on our website. Notifications will follow due process as per usual\****

**Notifying further products:** The system has been developed to allow a submitted notification to be used as a base template for future notifications allowing notifiers to submit a range of products swiftly and efficiently.

From the homepage, select edit submissions



Find the notification you have just submitted or want to duplicate and open by clicking the Case ID. The notification should load prepopulated with submission details.

**Submission Type: \***  
 -- Select a Submission Type --

**Company: \***  
 -- Select a Company --

**Submitter ID:**

**Product ID/EC ID: \***

EC-ID should be Submitter ID-last Two digit of year-Five digit Product Number

**Start Date:**  
 13 Mar 2019

**GENERATE SUBMITTER ID**

**Submission General Comment:**

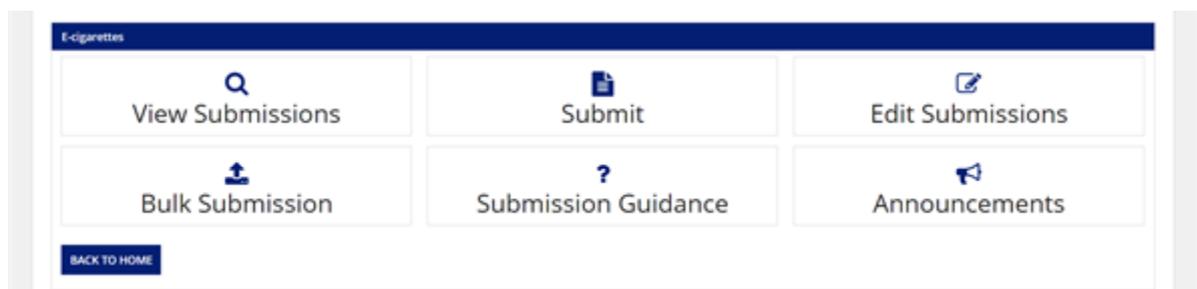
Select Submission Type 1 and enter your new product ECID by editing what has been prepopulated. Click Save Submitter Details, this will return you to the homepage (please wait 5 minutes for the data to refresh). Go back to Edit Submissions and find the new Product ECID which you have just created.

***\*Note: This notification will be prepopulated with information from the original notification, as such you will need to manually make amendments in this notification which will differentiate it from the original e.g. nicotine strength, capacity\****

## Section 3: How to view previous submissions

*Note: this section is strictly for viewing previous details and any changes will not be saved. Submitters can view ECIDs migrated from EU-CEG, however the full submission will not be available for viewing until providing the next product update. To make amendments to submissions, please see 'Section 4: How to submit updates'.*

To view previously made E-cigarette submissions, select 'View Submissions' from the E-cigarettes tile homepage.



You can filter your search using the dropdown menus or search fields seen below.

**CLOSE**

**E-cigarette SEARCH**

Product ID(EC-ID):  Product Type:  Submission Type:

Submission Comment:  Previous Product ID:  Status:

Submission Date:  Modified Date:

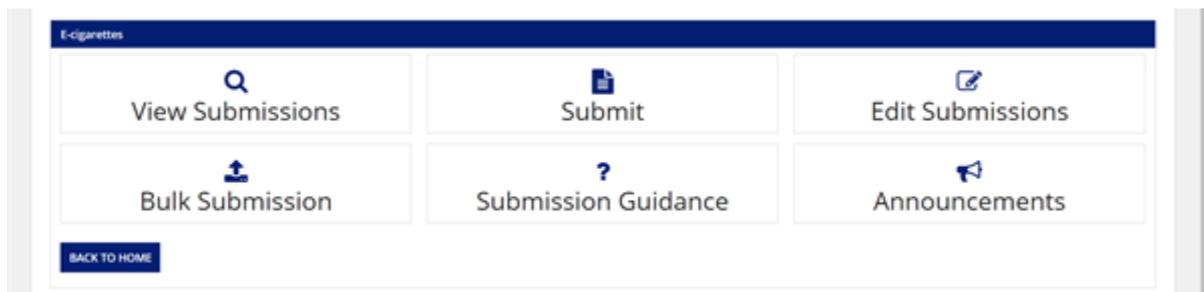
**SEARCH**

Case ID	Product ID(EC-ID)	Previous Product ID	Submission Date	Modified Date	Submission Type	Product Type	Submission Comment	Status
100183708	E551089-22-98765		07/03/2022	07/03/2022	Notification of information on a new product (new EC-ID)- TYPE 1	Electronic cigarette- Disposable		PENDING PAYMENT

To view a submission for an E-cigarettes product, select the case ID from the list below the search field.

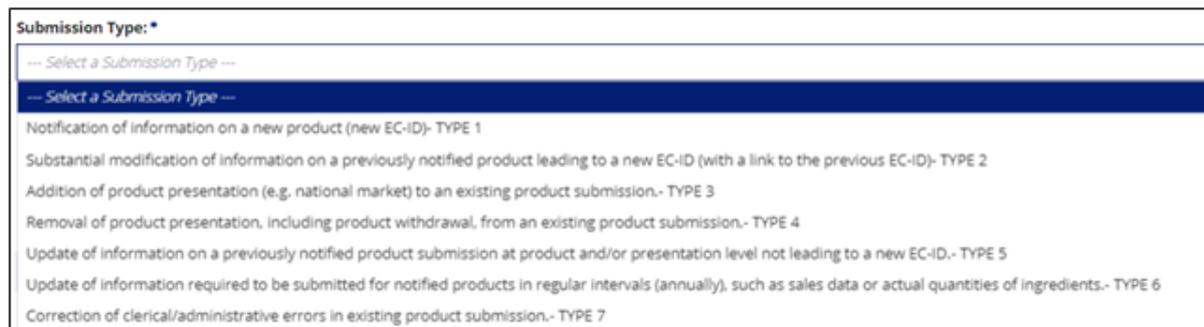
## **Section 4: How to submit updates**

Select 'Edit Submissions' from the E-cigarettes tile homepage.



Begin by selecting the relevant 'Submission Type' from the drop-down menu.

*\*Note: As a Type 1 submission has already been submitted for this product, it cannot be selected from the drop-down menu\**



*\*Note: Once you save submitter details the system will return you to the homepage (please wait 5 minutes for the data to refresh). Return to Edit Submissions and find the submission you were editing\**

You can then progress through the application, using steps in 'Section 1: How to make an E-cigarettes submission' as a guide where required, and make amendments where appropriate to your updated submission.

Progress to the 'Validate' tab once all updates have been completed and ensure all areas are validated with a green tick. Then select 'Submit'.

Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.

Submitter Info   Product Details   Product Presentation   Ingredients   Emission   Design   **Validate**   Submission Status   Payment/Published Data

Validate and Confirm

Submitters intending to supply a product to the Northern Ireland market must upload their notification via the European Common Entry Gate (EUCEG). Please see our webpage for guidance on EUCEG notifications. To receive the single fee discount for NI and GB submitters are required to notify products using matching ECIDs via EUCEG and MHRA portals.

Validation	Tab Title	Status
✓	<a href="#">Submitter Info</a>	This form is complete
✓	<a href="#">Product Details</a>	This form is complete
✗	<a href="#">Product Presentation</a>	Please fill all mandatory fields and Click on Save button
✗	<a href="#">Ingredients</a>	Please fill all mandatory fields and Click on Save button
✗	<a href="#">Emission</a>	Please fill all mandatory fields and Click on Save button
✗	<a href="#">Design</a>	Please fill all mandatory fields and Click on Save button

SUBMIT