



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information and Communications Technology

## MAH Simple Form

Tutorial

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# Introduction

The MAH Simple Electronic Reporting Form (MAHSERF) is a reporting module developed to be used by Marketing Authorisation Holders (MAH) with limited experience, and training in the direct reporting of adverse reaction reports using the EudraVigilance Veterinary Web Reporting Module (EVVET).

For many products at present, safety reports are sent only occasionally and the MAH is not in a position to get familiar with EVVET to ensure consistent data input. Such MAHs may, in agreement with the local competent authority, use the MAHSERF for the creation of an electronic report.

The MAHSERF is available via the websites of the Competent Authorities and on the EudraVigilance Veterinary central website. It is a web-based form available in most official EU languages and allows you to create an adverse reaction report related to a veterinary medicinal product using standard terminology. Some countries considered it sufficient to have the English version only. This report will be automatically attached to an e-mail that is sent to the competent authority of your choice. On receipt of this e-mail, the competent authority will further process and upload the information into the central EudraVigilance Veterinary database.

## 1. Creating a new Report Form

You will find a link to access the MAH Simple Electronic Reporting Form either on the EMA EudraVigilance Veterinary Website or on the website of the competent authority of your country.

1. Click on the link and the following page is displayed:



Either select 'Create New MAH Simple Reporting Form' for a blank form or if you want to load a previously saved XML file select 'Upload Saved MAH Simple Reporting Form'.

[Create New MAH Simple Reporting Form](#)

[Upload Saved MAH Simple Reporting Form](#)

2. To create a new form, click on “**Create a new MAH Simple Reporting Form**”.
3. Select the national competent authority to whom you wish to send the message, then select the language that you wish the form to be in (language available options dependent on the country previously chosen).

Please note that some competent authorities consider the availability of the English version to be sufficient.



Select Reporting Country

Select Language

[Continue >>](#)

In the example below, there is only the English choice for the United Kingdom, but for Belgium there would be three choices: Dutch, French, and English.



The screenshot shows a light green background with two dropdown menus. The first is labeled "Select Reporting Country" and has "United Kingdom" selected. The second is labeled "Select Language" and has "English" selected. Below the menus is a blue button with the text "Continue >>" in white.

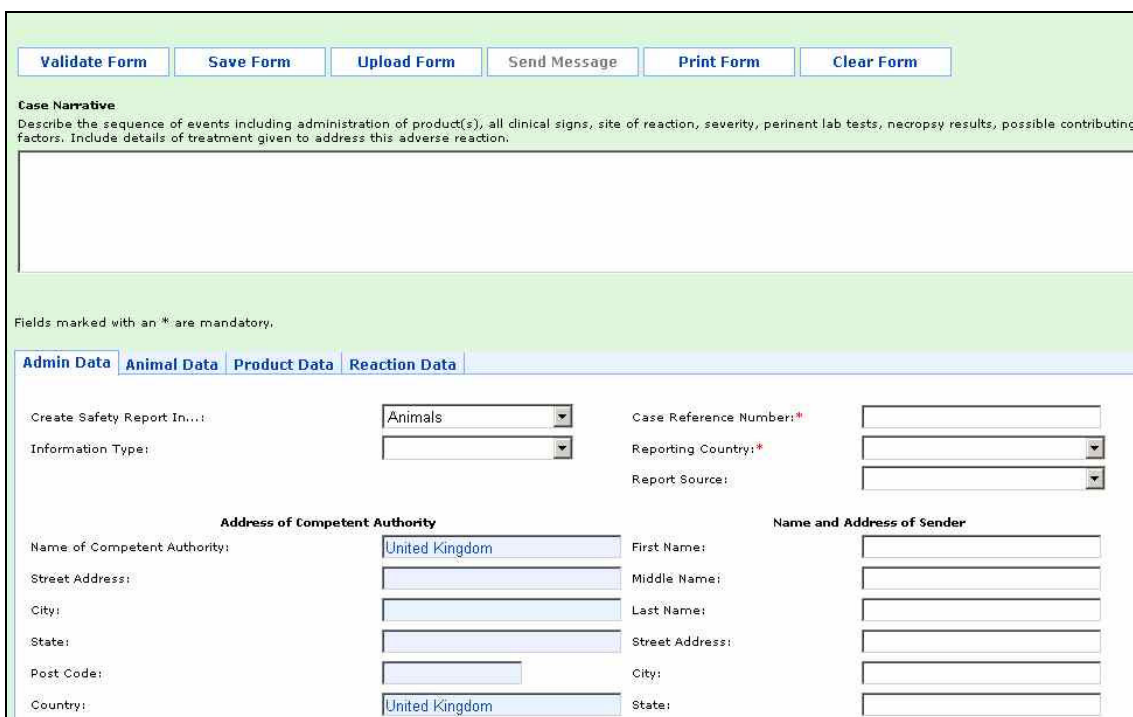
This is the first screen for the Simple form.

At the top of the form there is a row of buttons that allow you to perform various functions: **Validate**, **Save**, **Upload**, **Send**, **Print** and **Clear Form** and **XML**.

The "**Case Narrative**" box, situated at the top of the form is always visible, regardless which section of the form you are in.

The data entry part of the form is structured on a tab format. There are four tabs, each indicating a different section: **Administrative data**, **Animal Data**, **Product Data** and **Reaction Data**.

Some of the fields in the form are free-form text, others consist of drop-down boxes with standard terminology lists. The fields marked with a red \* are mandatory fields.



The screenshot shows the main data entry interface. At the top, there is a row of buttons: "Validate Form", "Save Form", "Upload Form", "Send Message", "Print Form", and "Clear Form". Below this is a "Case Narrative" section with a text area and a description: "Describe the sequence of events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors. Include details of treatment given to address this adverse reaction." Below the text area is a note: "Fields marked with an \* are mandatory." There are four tabs: "Admin Data", "Animal Data", "Product Data", and "Reaction Data". The "Admin Data" tab is active. It contains several fields: "Create Safety Report In..." (dropdown with "Animals"), "Information Type:" (dropdown), "Case Reference Number:\*" (text input), "Reporting Country:\*" (dropdown), and "Report Source:" (dropdown). Below these are two columns of fields. The left column is titled "Address of Competent Authority" and includes "Name of Competent Authority:" (dropdown with "United Kingdom"), "Street Address:", "City:", "State:", "Post Code:", and "Country:" (dropdown with "United Kingdom"). The right column is titled "Name and Address of Sender" and includes "First Name:", "Middle Name:", "Last Name:", "Street Address:", "City:", and "State:".

When filling the form, it is advisable to enter the **Case narrative** first, giving as much information as possible. The **Case narrative** remains visible in all sections of the form, therefore the information you have already entered there will help you when you are filling in the rest of the form.

**Case Narrative**  
 Describe the sequence of events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors. Include details of treatment given to address this adverse reaction.

03/07/05: Female dog (German Shepherd) started treatment with PainST 1.5 mg/ml Oral Solution for pain associated with arthritis. 10/07/05: Dog taken to clinic with inappetence, diarrhoea and vomiting. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 11/07/05: Dog died, owner refused necropsy.

Fields marked with an \* are mandatory.

Create Safety Report In...:  Case Reference Number:\*

Information Type:  Reporting Country:\*

Report Source:

Once you have entered the **Case narrative** start entering the **Administrative data**.

10/07/05: Dog taken to clinic with inappetence, diarrhoea and vomiting. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 11/07/05: animal recovered during the day and was sent home under medication. At the time of discharge blood values were normal.

Fields marked with an \* are mandatory.

Create Safety Report In...:  Case Reference Number:\*

Information Type:  Reporting Country:\*

Report Source:

**Address of Competent Authority** **Name and Address of Sender**

Name of Competent Authority:  First Name:

Street Address:  Middle Name:

City:  Last Name:

State:  Street Address:

Post Code:  City:

Country:  State:

First state whether the case you are reporting involves animals or humans, and then select the **Information type** from the drop-down menu.

Create Safety Report In...:  Case Reference Number:\*

Information Type:  Reporting Country:\*

Report Source:

**Address of Competent Authority** **Name and Address of Sender**

Name of Competent Authority:  First Name:

Street Address:  Middle Name:

Give the case a **Case Reference Number** in accordance with your internal numbering system, and enter the **Reporting Country** (country of origin of the primary source of the report) and the **Report Source** from the drop down menu.

Create Safety Report In...:	Animals	Case Reference Number:*	UK-Hollstein-12345
Information Type:	Safety issue	Reporting Country:*	United Kingdom
		Report Source:	
<b>Address of Competent Authority</b>		<b>Name and Address of Sender</b>	
Name of Competent Authority:	United Kingdom	First Name:	Veterinarian
Street Address:		Middle Name:	Pharmacist
City:		Last Name:	Other health professional
State:		Street Address:	Animal owner
		City:	Animal tender
		State:	Other
		Post Code:	Unknown
		Country:	

Enter you details under the sub-section **Name and Address of Sender**.

<b>Address of Competent Authority</b>		<b>Name and Address of Sender</b>	
Name of Competent Authority:	United Kingdom	First Name:	Mark
Street Address:		Middle Name:	
City:		Last Name:	Hendriks
State:		Street Address:	26 Coldport Road
Post Code:		City:	Endlock
Country:	United Kingdom	State:	
		Post Code:	EN3 7BP
		Country:	United Kingdom

State the date in which you received the report from the Primary source on **Date complaint received by sender**, and select the appropriate entry for **Person who reported the Reaction** from the drop-down list.

With regards to the next two sub-sections, enter the details of the original reporter (Veterinarian / Owner, etc) **only if acceptable under national law**.

Date Complaint Received by Sender(dd/mmm/yyyy):	12 Jul 2005	Person who reported the Reaction:	Veterinarian
<b>Veterinarian/Physician/Pharmacist</b>		<b>Animal Owner</b>	
First Name:		First Name:	
Middle Name:		Middle Name:	
Last Name:*		Last Name:	
Street Address:		Street Address:	
City:		City:	
State:		State:	
Post Code:		Post Code:	
Country:		Country:	
Telephone:		Telephone:	

The field **Last name** is mandatory in the sub-section Veterinarian / Physician. Therefore, if as a result of restrictions under your national legislation you are unable to provide this information, you can just enter the initial of the surname in this field.

Once you finalise entering the administrative data, proceed to the next section **Animal data** by clicking on the appropriate tab.

Enter the number of animals treated, and number of animals displaying signs.

05/07/05 Female German shepherd prescribed PainST 3 mg/ml oral solution for arthritis. 10/07/05: Dog taken to clinic with inappetence, diarrhoea and vomiting. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 11/07/05: Dog died, owner refused necropsy.

Fields marked with an \* are mandatory.

**Admin Data** **Animal Data** Product Data Reaction Data

No. of animals treated:  No. of animals showing signs:

**Animal characteristics (animal(s) showing signs):**

Species:\*

Breed:

Sex:  Weight (kilos):

Physiological status:  Age Group:

Age:  Age unit:

State of Health at time of Treatment:

In the next sub-section **Animal characteristics** the majority of the fields are drop-down boxes containing standard terminology lists. Choose the relevant information from the look ups provided

05/07/05 Female German shepherd, 10 years old, was prescribed PainST 3 mg/ml oral solution for arthritis. 10/07/05: Dog taken to clinic with inappetence, diarrhoea and vomiting. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 11/07/05: Dog died, owner refused necropsy.

Fields marked with an \* are mandatory.

**Admin Data** **Animal Data** Product Data Reaction Data

No. of animals treated:  No. of animals showing signs:

**Animal characteristics (animal(s) showing signs):**

Species:\*

Breed:

Sex:  Weight (kilos):

Physiological status:  Age Group:

Age:  Age unit:

State of Health at time of Treatment:

Once you have entered all the available information, go to the next section, **Product data**. This section is repeatable, to allow data entry for multiple products.

Fields marked with an \* are mandatory.

**Admin Data** **Animal Data** **Product Data** Reaction Data

Enter the details for the first product as complete as possible, as displayed in the example below:

The screenshot shows a web form for entering product details. At the top, there are buttons for "Add Product" and "Remove Product". Below that, a tab labeled "Product # 1" is active. The form contains several fields: "Trade name:" with the value "PainST 3 mg/ml Oral Solution"; "Dosage form:" with a dropdown menu set to "Oral solution"; "Strength:" with the value "3" and "Strength unit:" with a dropdown menu set to "milligram(s)/millilitre"; "M.A. number:" with the value "EU/2/99/055/001" and "Characterisation:" with a dropdown menu set to "Suspect"; "Active substance:" with the value "Silfingine" and "ATC vet code:" with a dropdown menu set to "QA" and a blue box with three dots next to it; "Batch number:" with the value "32556DC" and "Expiry date(mmm/yyyy):" with a dropdown menu set to "Jun" and a text field with "2007". Below these are "Treatment details" including "Dose/frequency:", "Start date(dd/mmm/yyyy):" (05 Jul 2005), "End date(dd/mmm/yyyy):", "Duration:", "Who administered the product:" (Animal owner), "Use according to label:" (Yes), and "Off label use:". At the bottom, there are fields for "Action taken after reaction:", "Attending veterinarians level of suspicion that product caused reaction:", "Causality assessment related to product" (Classification: B - Possible), and "Reason for classification:" (Gastrointestinal signs and acute renal failure are potential risks of NSAID therapy. However, as no further investigations (i.e. necropsy) have been performed to exclude alternative causes, this case has been assessed as B-possible).

To enter the ATC vet code, click on the blue box with the three dots that appears next to the field:



A drop-down menu will appear just below the **Product data** tab. Choose the appropriate ATC code from the list and press **Select**. The code is then displayed in the field.

The screenshot shows the "Product Data" tab selected in the "Product # 1" section. Below the "Add Product" and "Remove Product" buttons, there is a dropdown menu showing the ATC vet code "QA01AA30" and a "Select" button. The dropdown menu is open, showing a list of ATC codes. The text "Fields marked with an \* are mandatory." is visible at the top of the form.

If there are several products involved in the case you are reporting, click **Add product**. A new sub-section as a separate tab is available, where you can enter the information for Product # 2.

The screenshot shows a form for adding a product. At the top left, there are two buttons: 'Add Product' and 'Remove Product', both circled in red. Below them are two tabs: 'Product #1' and 'Product #2', with 'Product #1' also circled in red. The form contains several input fields and dropdown menus, including: Trade name\* (text), Dosage form (dropdown), Strength (text), Strength unit (dropdown), M.A. number (text), Characterisation (dropdown), Active substance (text), ATC vet code (dropdown with a search icon), Batch number (text), Expiry date (mmmm/yyyy) (text with dropdowns), Treatment details section with fields for Dose/frequency, Start date (dd/mmm/yyyy), Duration, Who administered the product, and Use according to label, and Route/site of administration, End date (dd/mmm/yyyy), and Duration unit.

Repeat this step as many times as the number of products you need to input.

Once you have entered the data for all relevant product(s), go to the **Reaction data** section.

The screenshot shows a navigation bar with four tabs: 'Admin Data', 'Animal Data', 'Product Data', and 'Reaction Data'. The 'Reaction Data' tab is highlighted in blue, indicating it is the active section.

First fill in the details of the reaction (date, duration...).

The screenshot shows the 'Reaction Data' section. At the top, there is a 'Case Narrative' section with a text area containing the following text: "05/07/05 Female German shepherd, 10 years old, was prescribed PainST 3 mg/ml oral solution for arthritis. 10/07/05 Dog not eating; in the afternoon started having diarrhoea and vomiting. PainST stopped. 11/07/05 Dog taken to clinic. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 12/07/05: Dog died, owner refused necropsy." Below this is a navigation bar with tabs for 'Admin Data', 'Animal Data', 'Product Data', and 'Reaction Data'. The 'Reaction Data' tab is active. Below the navigation bar is a section titled 'Details of suspected adverse reaction(s) in animals' with the following fields: Date of onset of signs (dd/mmm/yyyy): 10 Jul 2005, Duration of reaction: 1, Were the signs treated?: Yes, and Duration unit: Day.

Next, state all clinical signs present in the reaction by using the VedDRA Terms(s) look-up provided. This look-up contains all Low Level Terms (LLT) as specified in the latest version of the Guideline adopted by the CVMP.

To find a term in the look-up list, navigate through the list by clicking on any term to highlight it, then use the first letter of the word you need: i.e., to search for the VeDDRA term **Diarrhoea**, click once on any term so that it turns blue, for example "Abdominal cavity disorder NOS", then type the starting letter for the term you need to find, in this example the letter "d". The system will then take you to the beginning of the list for all terms starting with "d".

**Details of suspected adverse reaction(s) in animals**

Date of onset of signs (dd/mmm/yyyy): 10 Jul 2005

Duration of reaction: 1

Were the signs treated?: Yes

Duration unit: Day

VeDDRA Term(s):\*

- Abdominal cavity disorder NOS
- Abdominal cavity hernia
- Abdominal cramp
- Abdominal oedema
- Abdominal pain
- Abnormal birth weight
- Abnormal breathing

< >

**Details of suspected adverse reaction(s) in animals**

Date of onset of signs (dd/mmm/yyyy): 10 Jul 2005

Duration of reaction: 1

Were the signs treated?: Yes

Duration unit: Day

VeDDRA Term(s):\*

- Cystitis
- Deafness
- Deafness NOS
- Death
- Death by euthanasia
- Decreased appetite
- Decreased body temperature

< >

Scroll through the list until you find the required term. Once you have found the term click on it so that it becomes highlighted in blue, then click on the forward arrow as displayed in the following example:

**Details of suspected adverse reaction(s) in animals**

Date of onset of signs (dd/mmm/yyyy): 10 Jul 2005

Duration of reaction: 1

Were the signs treated?: Yes

Duration unit: Day

VeDDRA Term(s):\*

- Devitalisation
- Diabetes
- Diabetes insipidus
- Diabetes mellitus
- Diabetic coma
- Diarrhoea
- Digestive tract disorder NOS

< >

The term **Diarrhoea** will then be transferred to the box on the right hand side.

VeDDRA Term(s):\*

- Diabetes
- Diabetes insipidus
- Diabetes mellitus
- Diabetic coma
- Digestive tract disorder NOS
- Digestive tract haemorrhage NOS
- Digestive tract hypermotility

< >

Diarrhoea

Repeat this operation as many times as necessary until all the clinical terms present in the reaction appear in the box in the right hand side. **(If the animal or person that reacted dies /is euthanised, enter this event as a VeDDRA term).**

VeDDRA Term(s):*	Cystitis Deafness Deafness NOS Death by euthanasia Decreased appetite Decreased body temperature Decreased heart rate	<input style="border: none;" type="button" value=" &lt; "/> <input style="border: none;" type="button" value=" &gt; "/>	Diarrhoea Vomiting Abnormal test result Acute renal failure Death
------------------	---	---	---

Once a term has been selected and you decide that another choice would have been more appropriate, click on the term so that it is highlighted in blue, press the back arrow, and the term will be deleted from the box.

<input style="border: none;" type="button" value=" &lt; "/> <input style="border: none;" type="button" value=" &gt; "/>	Diarrhoea Vomiting Abnormal test result Acute renal failure Death
---	---

Vomiting Abnormal test result Acute renal failure Death
--

To finalise the data entry, fill in the rest of the details as required.

<b>Outcome of reaction to date:</b>			
No. of animals killed/euthanised:	<input type="text"/>	No. of animals died:	<input type="text" value="1"/>
No. of animals under treatment:	<input type="text"/>	No. of animals alive with sequelae:	<input type="text"/>
No. of animals recovered:	<input type="text"/>	No. of animals unknown:	<input type="text"/>
Did reaction abate after stopping drug?:	<input type="button" value="No"/>	Did reaction reappear after reintroduction?:	<input type="button" value=""/>
<b>Previous exposure and reaction to product</b>			
Previous exposure to this product?:	<input type="button" value=""/>	Previous reaction to this product?:	<input type="button" value=""/>
Describe previous reaction:			
<input style="width: 100%; height: 100%;" type="text"/>			

Once you have entered all available information, it is advisable to validate the form to check if all mandatory fields have been completed. Click on the **Validate Form** button on the toolbar at the top of the screen.

The screenshot shows the top toolbar of the MAH Simple Form. The 'Validate Form' button is circled in red. Below the toolbar is the 'Case Narrative' section, which contains a text area with the following text: '05/07/05 Female German shepherd, 10 years old, was prescribed PainST 3 mg/ml oral solution for arthritis. 10/07/05 Dog not eating; in the afternoon started having diarrhoea and vomiting. PainST stopped. 11/07/05 Dog taken to clinic. Blood tests showed elevated creatinine and BUN values. DVM diagnosed acute renal failure and the dog was treated with IV fluids and metaclopramine, and stayed in the clinic overnight. 12/07/05: Dog died, owner refused necropsy.' Below the text area is a note: 'Fields marked with an \* are mandatory.' At the bottom of the form, there are tabs for 'Admin Data', 'Animal Data', 'Product Data', and 'Reaction Data'.

The result of the validation in this example is that there are one or more mandatory fields that have not been completed:

This screenshot shows the MAH Simple Form with a validation error dialog box open. The dialog box, titled 'Microsoft Internet Explorer', contains a yellow warning icon and the text: 'Mandatory fields left blank. Please review your form completing all fields marked with the \* character.' Below the dialog box, the 'Details of suspected adverse reaction(s) in animals' section is visible, showing a date of onset of signs of '10 Jul 2005' and a 'treated?' dropdown menu set to 'Yes'. The 'Validate Form' button in the toolbar is highlighted.

Review the form to find the mandatory fields to input. Once you have completed the information, click on **Validate Form** again.

This screenshot shows the MAH Simple Form with a validation success dialog box open. The dialog box, titled 'Microsoft Internet Explorer', contains a yellow warning icon and the text: 'Validation Successful'. Below the dialog box, the 'Details of suspected adverse reaction(s) in animals' section is visible, showing a date of onset of signs of '10 Jul 2005' and a 'treated?' dropdown menu set to 'Yes'. The 'Validate Form' button in the toolbar is highlighted.

You can save the form by pressing **Save Form** on the toolbar.

To send the message to the competent authority, click on **Send Message** on the toolbar. An e-mail is created, with the dedicated e-mail address for the competent authority already completed, and the form that you have just filled in appears as an attachment.

The screenshot shows a web browser window titled "Send Veterinary Safety Report - Microsoft Internet Explorer". The browser's address bar and toolbar are visible at the top. The toolbar contains five buttons: "Validate Form", "Save Form", "Upload Form", "Send Message", and "Print". The main content area of the browser displays an email composition form with the following fields:

- From:** An empty text input field.
- To:** A text input field containing the email address "andy.cooper@emea.eu.int".
- CC:** An empty text input field.
- Subject:** An empty text input field.
- Attachment:** A text input field containing the file name "1208786103114108667578521148511211953114.xml".
- Message:** A large, empty text area for composing the email body.

At the bottom left of the form, there is a blue button labeled "Send". To the right of the form, there is a vertical scrollbar and some partially visible text from the underlying page, including "of reaction, sev", "ere the signs", "eated?:", and "uration unit:".

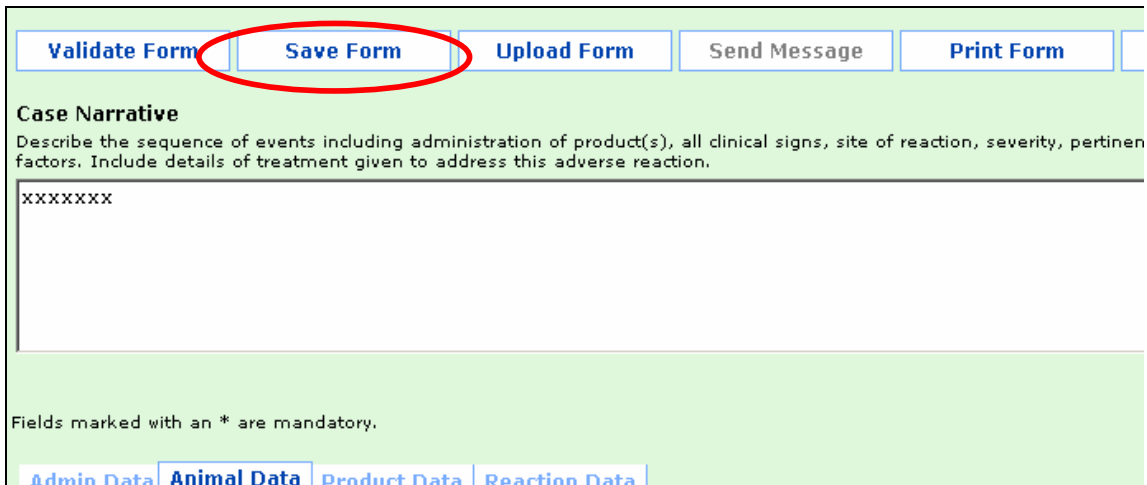
Type your e-mail address on the **From** field, add some further explanatory notes on the **Message body** and on the **Subject** field, and click **Send**.

## 2. Saving and Uploading a previously created Reporting Form

There may be occasions where you want save a form half-way through completing it, and then return to it at a later time to finish it.

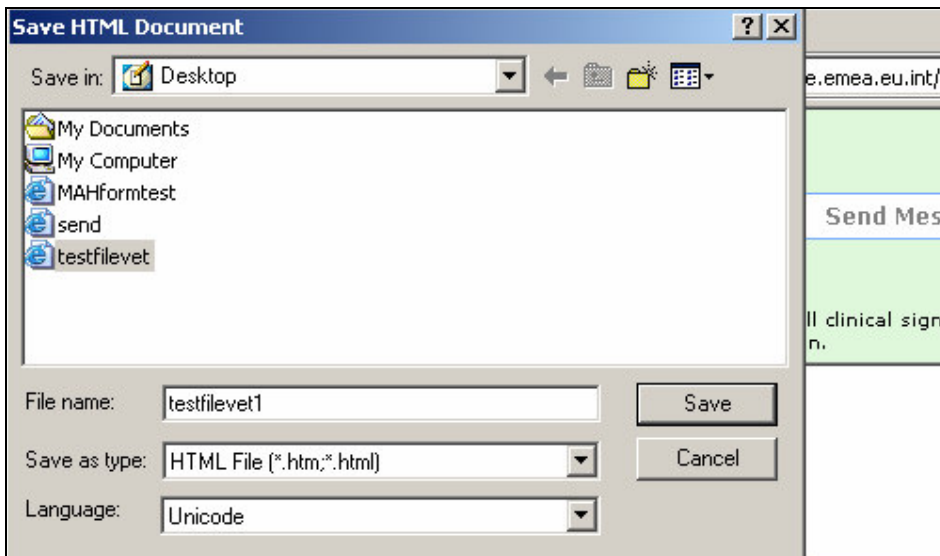
The procedure for saving the form is as follows:

1. Click on **Save Form**.



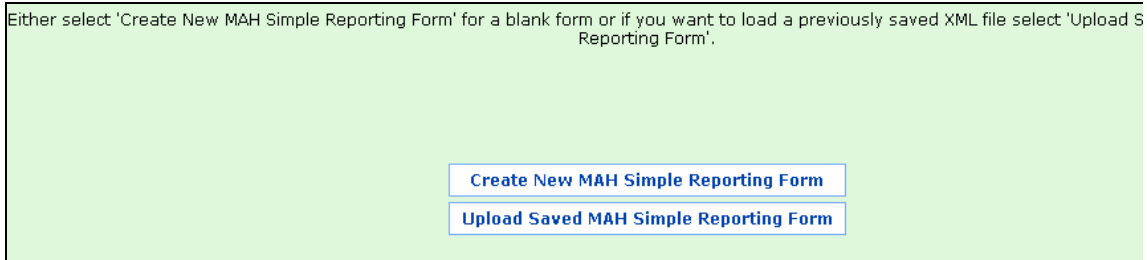
The screenshot shows the top navigation bar of the MAH Simple Reporting form. It contains five buttons: 'Validate Form', 'Save Form', 'Upload Form', 'Send Message', and 'Print Form'. The 'Save Form' button is highlighted with a red circle. Below the navigation bar is the 'Case Narrative' section, which includes a text area with the placeholder text 'xxxxxxx'. At the bottom of the form, there are tabs for 'Admin Data', 'Animal Data', 'Product Data', and 'Reaction Data'. A note at the bottom left states 'Fields marked with an \* are mandatory.'

2. Next, save the form wherever on your internal file system, as displayed in the following example:

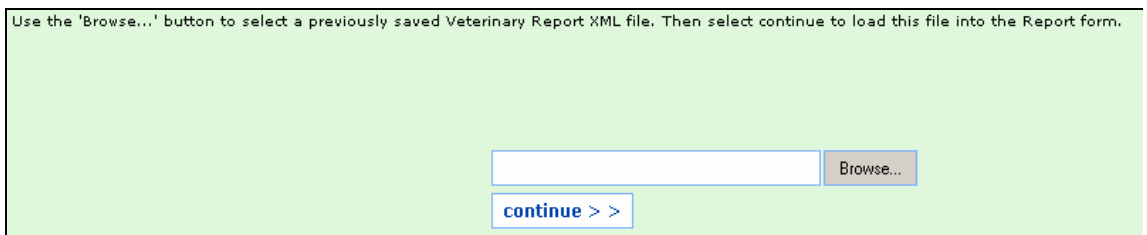


When you want to continue data entry, you need to log onto the website again with the opening page to the MAH Simple Reporting form.

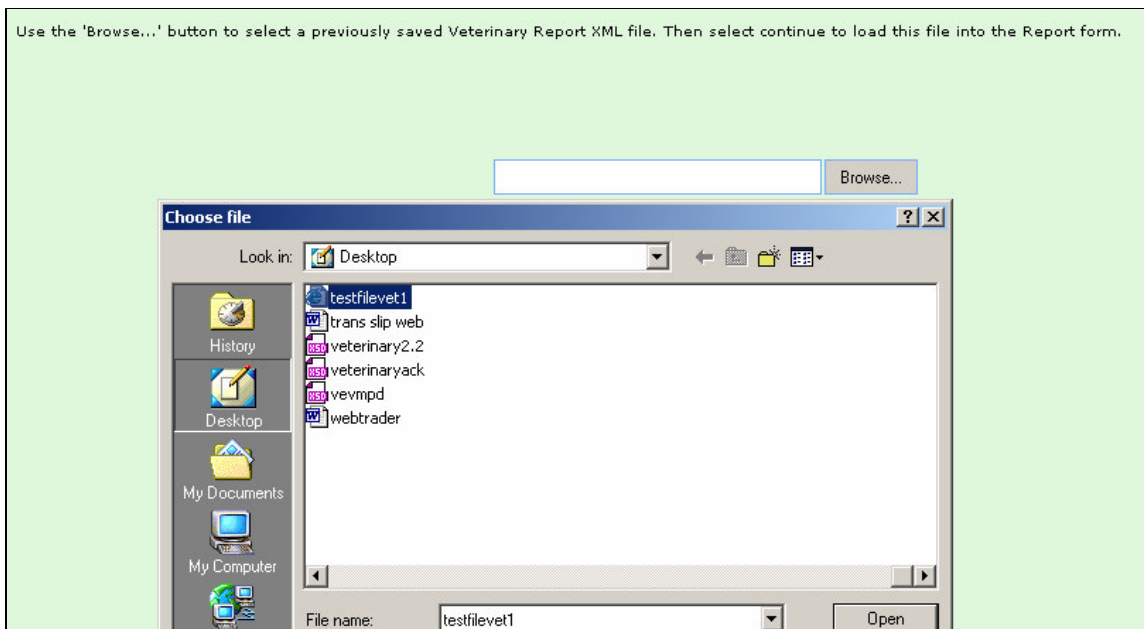
3. Click on the link and the following page will appear. Then, select **Upload Saved MAH Simple Reporting Form**:



4. Click on **Browse**, and you will be taken to your computer's file system.



5. In your system, select the previously saved file that you wish to continue completing, and press **Open**.



6. Click on **Continue**.

C:\Documents and Settings\patten Browse...

continue >>

7. Enter the **Reporting country** and the required language:

Select Reporting Country Test

Select Language English

Continue >>

8. Click on **Continue**, the file will be imported, and continue completing the data entry on the form.

Validate Form Save Form Upload Form Send Message Print Form Clear Form S

**Case Narrative**  
Describe the sequence of events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors. Include details of treatment given to address this adverse reaction.

xxxxxxx

fields marked with an \* are mandatory.

Admin Data Animal Data Product Data Reaction Data

Create Safety Report In...: Animals Case Reference Number:\* AF-xxx

Information Type: Safety issue Reporting Country:\* Afghanistan

### 3. Save as XML

In exceptional circumstances, and after previous agreement with the EMA, MAHs for Centrally Authorised Products will be able to use the MAH Simple Electronic Reporting Form to send SAR reports directly to the EMA. The EMA will provide those MAHs with a dedicated e-mail address; the MAH will send the Simple Electronic Form as an e-mail attachment in XML format, to allow direct import into EVVET.

To facilitate this process, there is a function on the MAH Simple Electronic Reporting Form to allow the user to save the form as an XML file.



Click on Save as XML. The system will take you to your computer file system, where you can save the file. You can then attach this file to an e-mail and send it to the dedicated e-mail address that will be supplied to you by the EMA.



## 4. Sending Safety Reports: additional security

Reports created using the MAH Simple Electronic Reporting Form are attached to an e-mail and this then sent using standard email. To use a more secure method of transmission, use the following method:

- Fill in all necessary data in the form, then save the form in your local system as an XML file by using the Save as XML function (see pg 18). You can then use a secure system such as Eudralink to send the file to the relevant Competent Authority to the dedicated e-mail address. Alternatively, the file can be saved onto physical media such as a CD and sent using post.

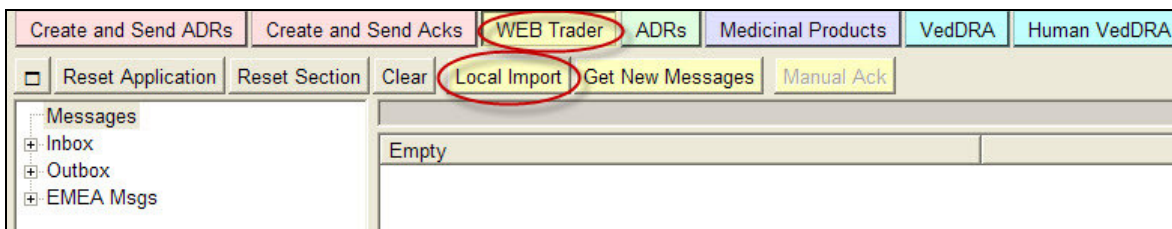
For further information regarding Eudralink please contact the Eudralink helpdesk at:

[Eudralink@ema.europa.eu](mailto:Eudralink@ema.europa.eu)

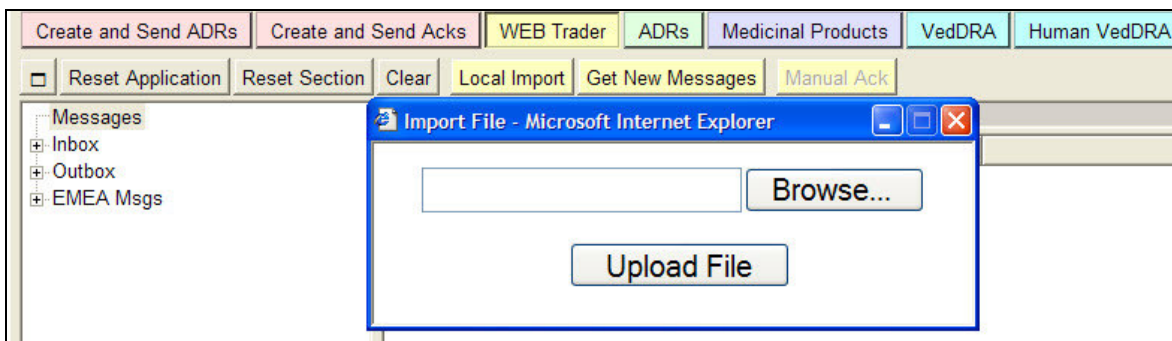
## 5. For CA - Upload in EVWEB a SAR report received via the MAH Simple Electronic Reporting Form

You will receive the SAR report via e-mail as an attachment, in XML format. Save this attachment in your computer system (desktop, filing system, etc).

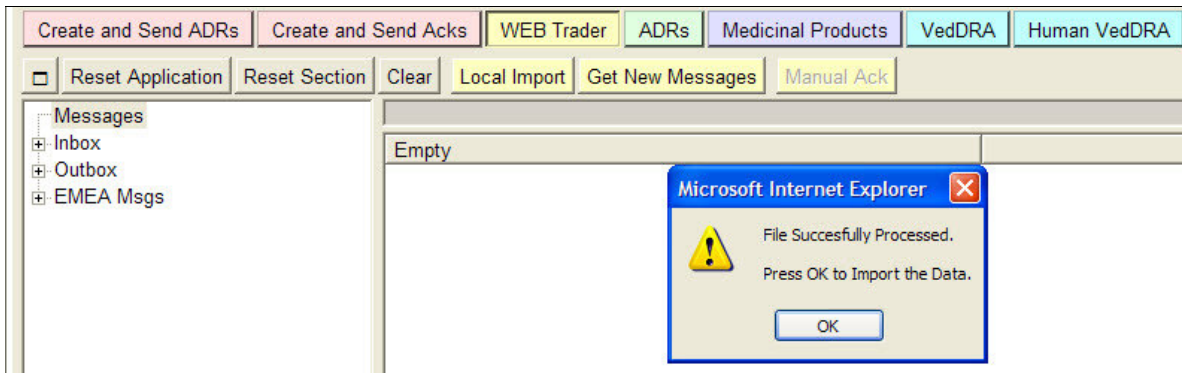
To upload the file in EVWEB for processing, open EVWEB, go to **WEB Trader**, and click on **Local Import**.



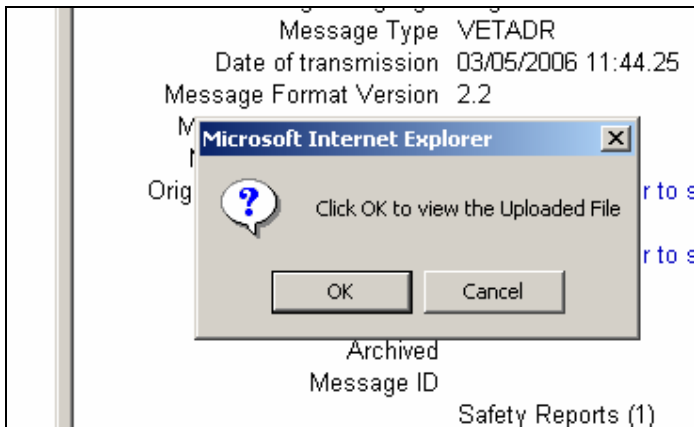
The following screen is displayed. Click **Browse**. This will take you to your computer file system. Find the attachment that you have previously saved, and click **Upload file**.



The following message will appear on the screen. Press **OK**.



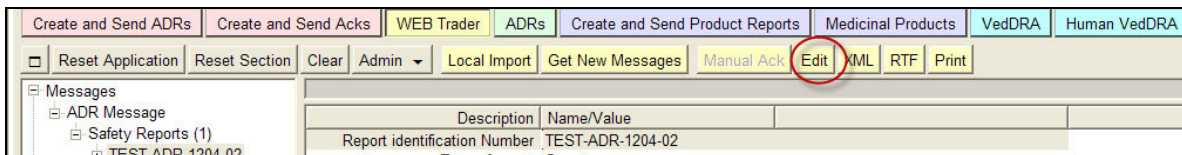
You will then see the message below. Do not click **OK** as this function only takes you to the **XML** version of the message without uploading. Click on **Cancel**, the attachment will then be uploaded in EVWEB.



Open the tree view (on the left hand side of the screen) by clicking on the "+" signs next to **ADR message** and **Safety reports**, and click on the report number so that it turns blue.

You will see that the toolbar changes, and the button **Edit** appears on the screen.

Click on **Edit**.



The SAR report will then be transferred to the **Send ADRs** section, where you can edit the information provided by filling in the necessary details, and/or adapt certain data. Please note that the Simple Electronic form does not contain all the fields available in EVWEB, therefore some information may have to be extracted from the narrative. After validation, the ADR can then be sent to the EV system following the usual procedures.

Microsoft Internet Explorer

Message Receivers:  
Eudravigilance Veterinary  
OK to Send ?

OK Cancel

Microsoft Internet Explorer

Message Receivers:  
Eudravigilance Veterinary  
OK to Send ?

OK Cancel

Message

Safety Reports

TEST-ADR-1204-02

BovCa

Animal data

Duplicatereports (-)

Literature references (-)

Clinical trials (-)

Linked reports (-)

Primary source

Other peoples (-)

Message Receivers

Last Message Receivers -

United Kingdom (GB) - Eudravigilance

Create and Send ADRs Create and Send Acks WEB Trader ADRs Create and Send Product Reports Medicinal Products VedDRA Human VedDRA

Reset Application Reset Section Clear Admin Validate Send ML RTF E R DSQL

Description	Name/Value
Message Number	234
	Safety Reports
	Message Receivers