

6 April 2018 EMA/467742/2014 Information Management

# eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Step-by-Step Guide

Insert of an Organisation

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# All examples used in this step-by-step guide are fictitious and intended for demonstration purposes only.

## 1.1. Organisation Example specification

For the purpose of this step-by-step exercise, you will be inserting:

A marketing authorisation holder organisation with the details:

PharmeX 43 Winston Road London E14 5EU UK PharmeX@pharmex.co.uk A **sponsor organisation** with the details:

EraLab Lockington Close Margate MA12 4JJ UK

EraLab@eralab.com

#### Additional information

• The MAH is a medium size organisation with SME number EMA/SME/000/00/02.

## 1.2. Create an XEVPRM

1) Log in to the requested EVWEB environment:

EVWEB production: <u>https://eudravigilance.ema.europa.eu/x</u>

XCOMP (test) environment: <u>https://evtest.ema.europa.eu/x</u>

EVWEB training environment: <u>https://eudravigilance-training.ema.europa.eu/x/</u>



In the restricted area, click on "EVWEB":

Eudra <b>Vigila</b> Human Restricted	nce)		
EV Services	Pharmaceutical Industrie	es and Commercial Sponsors	
<ul> <li>EVWEB</li> <li>xEVMPD Export</li> </ul>	Please select the initial of th A B C D E F G H I J K	e Organisation ID:  L M N O P Q R S T U V W Y Z 0-9	
► EV Post	Regulators		
EV Registered Partners Manage your profile QPPV List Organisations List	Organisation Name	Organisation ID	Country
User Support  Help Desk  EVWEB Troubleshooting  XEVMPD Data-Entry Tool (EVWEB) User Manual_version 5.0  Change Password			

You are now logged in EVWEB – the organisation ID under which you are logged in is shown in the top right corner:

Display Settings	•						dcmtestmahtt (DCMTESTMAH) @ Human Product
Create and Send ICSRs	Create and Send Acks	WEB Trader	<b>ICSR5</b>	Create and Send Product Reports	Medicinal Products	MedDRA	
Reset Application Re	eset Section Clear						
				1			

#### 2) Go to "Create and Send Product Reports" section:

ſ	Create and Send ICSRs Create and Se	nd Acks	WEB Trader	ICSRs	Crea	ate and Send Product R	eports	Medicinal Products	MedD	RA	
	Reset Application     Reset Section     Clear     Validate     Send     XML     ZIP     RTF     E     L     R										
	XEVPRM Message										
			De	scription	Name/\	Value					
	Message Number						Field is	Mandatory			
					Products						
					Substances						
					Sources	s					
					Organis	ations					
					ATC Codes						
						Pharmaceutical Forms					
					Routes	Of Administration					
1					Master	File Locations					
					Attachn Master	nents File Locations					

3) With your mouse, click on the area next to the "Message Number". It is a free-text field. The area will become highlighted in blue:

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Crea	ate and Send Product R	eports	Medicinal Products	MedDRA		
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R										
		Des	cription	Name/\	Value					
		Message I	Number			Field is	Mandatory			
			I	Product	ts					
				Substar	nces					
			:	Sources	S					
			(	Organisations						
			/	ATC Codes						
		I	Pharmaceutical Forms							
			I	Routes	Of Administration					
			/	Attachn	nents					
			I	Master	File Locations					

4) Press "Enter" on your keyboard or click on the "E" ("Text Edit") button. Both actions will activate the field and allow you to write the name you wish to assign to you XEVPRM:

Create and Send ICSRs Create and Send	Acks WEB Trader ICSRs	Create and Send Product Re	eports Medicinal Products MedDRA				
Reset Application Reset Section Clear	r Validate Send XML ZIP	RTF E L R					
		Text Edit					
	Description	Name/Value					
	Message Number		Field is Mandatory				
		Products					
		Substances					
		Sources					
		Organisations					
		ATC Codes					
		Pharmaceutical Forms					
		Routes Of Administration					
		Attachments					
		Master File Locations					

5) Type in the message number you wish to assign to your XEVPRM, then press "Enter" on your keyboard:

Create and Send ICSRs Create and Ser	nd Acks WEB Trader	ICSRs	Create and Send Product	Reports	Medicinal Products	MedDRA			
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R									
	Descr	iption Na	ime/Value						
	Message Nu	ımber Ins	ert MAH and sponsor						
		Pro	oducts						
		Su	bstances						
		So	urces						
		Org	ganisations						
		AT	C Codes						
		Ph	armaceutical Forms						
		Ro	utes Of Administration						
		Att	achments						
		Ma	ister File Locations						

6) Expand the tree-view area by clicking on the "+" sign and select "Organisations" or double click on "Organisations" in the active area:

Create and Send ICSRs (	Create and Send Acks WEB Trade	er ICSRs	Create and Send Product Repo	rts Medicinal Products	MedDRA				
Reset Application     Reset Section     Clear     Validate     Send     XML     ZIP     RTF     E     L     R									
■ XEVPRM Message									
	C	escription N	ame/Value						
	Messaç	je Number 🔤	sert MAH and sponsor						
		Pr	oducts						
		Su	Ibstances						
		Sc	ources						
		Or	ganisations						
		AT	C Codes						
		Ph	armaceutical Forms						
		Ro	outes Of Administration						
		At	tachments						
		Ma	aster File Locations						

# 1.2.1. Marketing authorisation holder (MAH) organisation

7) Select "New MAH " by ticking the relevant box:

Create and Send ICSRs Create and Send	nd Acks WEB Trader ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Cle	ear Validate Send XML ZIP	RTF E L R		
□ XEVPRM Message				
Products	Num	Operation Type	Type	Organisation Name
Substances	New MAH			
	New Sponsor			
ATC Codes				
Pharmaceutical Forms				
-Routes Of Administration				
Attachments				
Master File Locations				

TI	+ !			-II I	±1	£! - I - I -		£				- ·- + ! + · ·
INP	active	area	\\//111	aisniav	TNA	TIPINS	relevant	TOF	an	NAAH	organisation	entity
1110	active	arca	***	alsplay	LI IC	noida	rerevant	101	an		organisation	CITCILY.
											5	

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs Create and Send Prod	uct Reports Medicinal Products MedDRA
Reset Application Reset Section Cl	ear Validate Send XML ZIP RTF Duplicate Rem	ove E L R
⊡-XEVPRM Message		
Products	Description Name/Value	
Substances	Operation Type Insert (1)	
Sources	EV Code	
Organisations	Type MAH (1)	
Insert (1) - MAH (1)	MAH Name	Field is Mandatory
AIC Codes	SME Status	
Pharmaceutical Forms	SME Number	
Attachments	MAH Sender ID	C. L. M. L.
Master File Locations	Address	Field is Mandatory
	Pagion	Field is Mandatory
	Postcode	Field is Mandatory
	Country Code	Field is Mandatory
	Tel Number	, isia to indificationy
	Tel Extension	
	Tel Country Code	
	Fax Number	
	Fax Extension	
	Fax Country Code	
	E-mail Address	
	Comment	

- The "Operation type" field displays "Insert (1)" as a default. It is not possible to assign a different operation type.
- > Mandatory fields that must be populated are highlighted with the text "Field is Mandatory".
  - Please note that not all mandatory fields are highlighted this way (some fields are business rules dependent). Additional mandatory fields/fields that must contain specific value may be highlighted during the validation process (see section 1.3.)
  - When information is entered in the individual mandatory fields, the text "Field is Mandatory" disappears.
  - Some of the fields contain look-up tables with pre-defined values. These values will be displayed if you press "Enter" on your keyboard.

Enter the relevant information in the individual fields **as per guidance provided for each field in** <u>Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance;</u> section 1.6. Initial Submission of a Marketing Authorisation Holder (MAH) Organisation.

#### 1.2.1.1. EV Code

The EV Code field is a field which will automatically display the assigned EV Code if maintenance related operation (i.e. NOT an insert) is performed. In your example, this field is blank because you are performing an insert of an entity.

#### 1.2.1.2. Type

The value in the "Type" field is automatically set to "MAH" as per your selection.

#### 1.2.1.3. MAH Name

This is a free-text field.

Using your mouse, click on the area next to "MAH Name". The area will become highlighted in blue:

Create and Send ICSRs Create and Ser	nd Acks WEB Trader	ICSRs Create and Send Pr	oduct Reports Medicinal Products	MedDRA
Reset Application Reset Section Cle	ar Validate Send X	KML ZIP RTF Duplicate Re	emove E L R	
⊡-XEVPRM Message				
Products	Description	Name/Value		
Substances	Operation Type	Insert (1)	_	
- Sources	EV Code			
⊡rorganisations	Туре	MAH (1)		
ATC Codes	MAH Name		Field is Mandatory	
- Pharmaceutical Forms	SME Status SME Number			
Routes Of Administration	MAH Sender ID			
Attachments	Address		Field is Mandatory	
Master File Locations	City		Field is Mandatory	
	Region			
	Postcode		Field is Mandatory	
	Tel Number		Field is Mandatory	
	Tel Extension			
	Tel Country Code			
	Fax Number			
	Fax Extension			
	Fax Country Code			
	Comment			

Press "Enter" on your keyboard or use the "E" ("Text Edit") button. Both actions will activate the field and allow you to write your text:

Create and Send ICSRs Create and	d Send Acks WEB	Trader ICS	Rs Creat	e and Send Produ	ict Reports	Medicinal Products	MedDRA
Reset Application Reset Section	Clear Validate	Send XML	ZIP RTF	Duplicate Remov	ve E L I	R	
⊡-XEVPRM Message							
Products	D	escription Nam	o//aluo				
Substances	Opera	tion Type Inse	(1)				
Sources	Opera	EV Code	.(1)				
□ Organisations		Type MAH	(1)				
Insert (1) - MAH (1)	M	AH Name	1	F	Field is Mandat	tory	
AIC Codes	SN	IE Status					
Pharmaceutical Forms	SME	E Number					
Routes Of Administration	MAH	Sender ID		_			
Mester File Leastions		Address		F	ield is Manda	tory	
Master File Locations		City		F	-ield is Mandat	tory	
		Region		E	ield in Mandat	ton.	
	Cou	ntry Code		F	Field is Mandat	tony	
	Te	l Number			Telu is Mariua	lory	
	Tel E	Extension					
	Tel Cou	ntry Code					
	Fa	x Number					
	Fax B	Extension					
	Fax Cou	ntry Code					
	E-mai	Address					
		Comment					

Type in the requested text and press "Enter" on your keyboard. The name of your MAH will be displayed in the "MAH Name" field:

Create and Send ICSRs Create and Sen	Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Cle	ar Validate Send XML ZIP RTF Duplicate Remove E L R
-XEVPRM Message -Products -Substances -Sources	Description Name/Value Operation Type Insert (1) EVCode
Organisations     Insert (1) - MAH (1) - PharmeX     ATC Codes     Pharmaceutical Forms     Routes Of Administration     Attachments	Type MAH (1) MAH Name PharmeX SME Status SME Number MAH Sender ID Address Eield is Mandatony
Master File Locations	City Field is Mandatory Region Postcode Field is Mandatory
	Country Code Field is Mandatory Tel Number Tel Extension Tel Country Code Fax Number
	Fax Extension Fax Country Code E-mail Address Comment

### 1.2.1.4. SME status

The "SME Status" field is a field that will allow you to select one of the available pre-defined values.

Using your mouse, click on the area next to "SME Status". The area will become highlighted in blue:

Cr	eate and Send ICSR	s Create and	Send Ack	s WE	B Trader	IC	SRs	Crea	ate and Ser	nd Pro	duct Reports	Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Rer	move E L	R	
⊡ ·· X	EVPRM Message												
	Products			r	)escription	Nar	ne/Val	110					
	Substances			0000	ation Type		rt (1)	uc					
	Sources			Oper	EV Code	5 11130	ar (1)						
ļ	Organisations				Type	, MAI	H (1)						
	Insert (1) - MAH (	1) - PharmeX		N	IAH Nam	Pha	rmeX						
	ATC Codes			S	ME Status	6							
	Pharmaceutical Form	ns		SM	IE Numbe	r							
	-Routes Of Administr	ation		MAH	Sender IE	)							
	Attachments				Address	6					Field is Mand	atory	
	Master File Location	s			Cit	/					Field is Mand	atory	
					Regio	1							
					Postcode	9					Field is Mand	atory	
				Cou	intry Code	9					Field is Mand	atory	
				T-1	el ivumbe	r							
				Tel Cer	Extension	1							
				F	av Numbo	r							
				Fax	Extension	' 1							
				Fax Co	intry Code								
				E-ma	il Addres								
					Commen	t							

Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:

Create and Send ICSRs Create and Sen	nd Acks WEB Trader	CSRs Create and Send Product	Reports Medicinal Products MedDRA
Reset Application Reset Section Cle	ear Validate Send XML	ZIP RTF Duplicate Remove	ELR
E-XEVPRM Message			
Substances	Description Na	ame/Value	
Sources	Operation Type Ins EV Code	ert (1)	
	Type M/ MAH Name Ph SME Status	AH (1) armeX	
Pharmaceutical Porms Routes Of Administration Attachments	SME Number MAH Sender ID Address	Select option	tory
Master File Locations	City Region Postcode	Press A - Z to find initial lette Press Enter to select, Escape to	tory er clear tory
	Tel Number	Medium (4)	tory
	Tel Country Code	Micro (2)	
	Fax Number Fax Extension	NA (1)	
	E-mail Address	Small (3)	

Using your mouse, select the requested value. It will become highlighted in black:



Once you click on the selected value, it will be displayed in the "SME Status" field:

Create and Send ICSRs Create and Ser	nd Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Cle	ear Validate Send XML ZIP RTF Duplicate Remove E L R
⊡ XEVPRM Message	
Products	Description Name/Value
Substances	Operation Type Insert (1)
Sources	EV Code
Organisations	Type MAH (1)
ATC Codes	MAH Name PharmeX
	SME Status Medium (4)
-Routes Of Administration	SME Number
Attachments	MAR Sender ID Address
Master File Locations	City Eield is Mandatory
	Region
	Postcode Field is Mandatory
	Country Code Field is Mandatory
	Tel Number
	Tel Extension
	Tel Country Code
	Fax Extension
	Fax Country Code
	E-mail Address
	Comment

#### 1.2.1.5. SME Number

This is a free text field.

Should you wish to enter an SME number, you can do so by clicking on the area next to the "SME Number". The area will become highlighted in blue:

Create and Send ICSRs Create and Se	end Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products M	MedDRA
Reset Application Reset Section Cl	ear Validate Send XML ZIP RTF Duplicate Remove E L R	
⊡-XEVPRM Message		
Products	Description Name/Value	
Substances	Operation Type Insert (1)	
Sources	EV Code	
⊡ Organisations	Type MAH (1)	
Insert (1) - MAH (1) - PharmeX	MAH Name PharmeX	
AIC Codes	SME Status Medium (4)	
Pharmaceutical Forms	SME Number	
Routes Of Administration	MAH Sender ID	
Attachments	Address Field is Mandatory	
·····Waster File Locations	City Field is Mandatory	
	Region Destando	
	Posicode Field is Mandatory	
	Tol Number	
	Tel Country Code	
	Fax Number	
	Fax Extension	
	Fax Country Code	
	E-mail Address	
	Comment	

Press "Enter" on your keyboard or click on the the "E" ("Text Edit") button. Both actions will activate the field and allow you to write your text:

Create and Send ICSRs Create and Se	d Acks WEB Trader ICSRs Create and Send Product Rep	oorts Medicinal Products MedDRA
Reset Application Reset Section Cl	ar Validate Send XML ZIP RTF Duplicate Remove E	LR
⊡-XEVPRM Message		
Products	Description Name/Value	
Substances	Operation Type Insert (1)	
Sources	EV Code	
⊡ Organisations	Type MAH (1)	
Insert (1) - MAH (1) - PharmeX	MAH Name PharmeX	
AIC Codes	SME Status Medium (4)	
Pharmaceutical Forms	SME Number	
Routes Of Administration	MAH Sender ID	
Attachments	Address Field is	Mandatory
Waster File Locations	City Field is	Mandatory
	Region Destende	Mandatas
	Posicode Field is	Mandatory
	Tel Number	Manuatory
	Tel Country Code	
	Fax Number	
	Fax Extension	
	Fax Country Code	
	E-mail Address	
	Comment	

Once you type in the required text, press "Enter" on your keyboard. The text will be displayed in the "SME Number" field:

Create and Send ICSRs Create and Se	nd Acks WEB Trader	ICSRs Create and Send F	Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Cl	ear Validate Send X	ML ZIP RTF Duplicate F	Remove E L R	ł	
⊡ XEVPRM Message					
Products	Description	Name/Value			
Substances	Operation Type	Insert (1)			
Sources	EV Code				
Organisations	Туре	MAH (1)			
ATC Codes	MAH Name	PharmeX			
Pharmacoutical Forms	SME Status	Medium (4)			
- Routes Of Administration	SME Number	EMA/SME/000/00/02			
Attachments	MAH Sender ID		Field in Mondate		
Master File Locations	City		Field is Mandato	ory	
	Region		T ford to Mandate	ory.	
	Postcode		Field is Mandate	ory	
	Country Code		Field is Mandate	ory	
	Tel Number				
	Tel Extension				
	Tel Country Code				
	Fax Number				
	Fax Extension				
	E-mail Address				
	Comment				

#### 1.2.1.6. MAH Sender ID

This is a free text field.

As per the guidance provided in <u>Chapter 3.11: Extended EudraVigilance product report message</u> (XEVPRM) user guidance; section 1.6. Initial Submission of a Marketing Authorisation Holder (MAH) Organisation, the organisation ID that corresponds to the same organisation as assigned in the EudraVigilance registration system may be provided.

Should you wish to enter the organisation ID in this field, use the same process as described in section *1.2.1.3. MAH Name.* 

#### 1.2.1.7. Address, City, Region and Postcode

These are free-text fields.

To enter the requested information in these fields, use the same process as described in section *1.2.1.3. MAH Name.* 



#### 1.2.1.8. Country Code

The "Country Code" field is a field that will allow you to select one of the available pre-defined values. Using your mouse, click on the area next to "Country Code". The area will become highlighted in blue:



Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:

Create and Send ICSRs Create and Ser	d Acks WEB Trader	1000 II 0 0 D		Medicinal Products	MedDRA
		Select option	_		
Reset Application Reset Section Cle	ar Validate Send XM	Press A - Z to find initial letter		R	
		Press Enter to select, Escape to clear	_		
Products	Description   N	Afghanistan (AE)			1
Substances	Description In				
Sources	Operation Type In				
□ Organisations		Albania (AL)	Ξ		
Insert (1) - MAH (1) - PharmeX	MAH Name F	h ligeria (D2)			
ATC Codes	SME Status N	American Samoa (AS)			
Pharmaceutical Forms	SME Number E	Andorra (AD)			
Routes Of Administration	MAH Sender ID	Angola (AO)			
Attachments	Address 4	Anguilla (AI)			
Master File Locations	City L	Antarctica (AQ)			
	Region Postcode F	Antigua And Barbuda (AG)			
	Country Code	Argentina (AR)		tory	
	Tel Number	Armenia (AM)		,	
	Tel Extension	Aruba (AW)			
	Tel Country Code	Australia (AU)	il I		
	Fax Number	Austria (AT)	il I		
	Fax Extension	Azerbaijan (AZ)			
	F-mail Address	Bahamas (BS)			
	Comment	Bahrain (BH)			
	- Commone				

Using your mouse.	select the requested	value. It will become	highlighted in black:
coming jour mouse,			inginighteed in black

Create and Send ICSRs Create and Sen	nd Acks WEB Trader	Select ontion	Medicinal Products MedDRA
Reset Application Reset Section Cle	ear Validate Send XML	Press A - Z to find initial letter Press Enter to select, Escape to clear	R
⊡-XEVPRM Message		Tanzania (12)	
Substances	Description Na	Thailand (TH)	
Sources	Operation Type Ins	TIMOR-LESTE (TL)	
	Ev Code Type M4	Togo (TG)	
Insert (1) - MAH (1) - PharmeX	MAH Name Ph	Tokelau (TK)	
ATC Codes	SME Status Me	Tonga (TO)	
Pharmaceutical Forms	SME Number EN	Trinidad And Tobago (TT)	
Attachments	MAH Sender ID	Tunisia (TN)	
Master File Locations	Address 43 City Lo	Turkey (TR)	
	Region	Turkmenistan (TM)	
	Postcode E1	Turks And Caicos (TC)	
	Country Code	Tuvalu (TV)	tory
	Tel Number	Uganda (UG)	
	Tel Country Code	Ukraine (UA)	
	Fax Number	United Arab Emirates (AE)	
	Fax Extension	United Kingdom (GB)	
	Fax Country Code	United States (US)	
	E-mail Address	United States Minoroutlying Islands	
	Comment	(UM)	

Once you click on the selected value, it will be displayed in the "Country Code" field:

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Cl	ear Validate Send XML ZIP RTF Duplicate Remove E L R
⊡-XEVPRM Message	
Products	Description Name/Value
Substances	
Sources	Operation type insert (1)
. Organisations	
Insert (1) - MAH (1) - PharmeX	MAH Name Dharmey
ATC Codes	SME Status Madium (A)
Pharmaceutical Forms	SME Number EMA/SME/00/00/02
-Routes Of Administration	MAH Sender ID
Attachments	Address 43 Winston Road
Master File Locations	City London
	Region
	Postcode E14 5EU
	Country Code United Kingdom (GB)
	Tel Number
	Tel Extension
	Tel Country Code
	Fax Number
	Fax Extension
	Fax Country Code
	E-mail Address
	Comment

# 1.2.1.9. Tel Number, Extension, Country Code, Fax Number, Fax Extension, Fax Country Code and E-mail address

These are free-text fields.

Should you wish to enter the requested information in these fields, use the same process as described in section *1.2.1.3. MAH Name*.

#### 1.2.1.10. Comment

This is a free- text field, in which information can be entered using the same process as described in section *1.2.1.3. MAH Name*.

As per business rules and guidance provided in <u>Chapter 3.11: Extended EudraVigilance product report</u> <u>message (XEVPRM) user guidance</u>; section *1.6. Initial Submission of a Marketing Authorisation Holder (MAH) Organisation*, no information should be entered in this field in this particular case.

You have now populated the fields for an MAH organisation entity "PharmeX":

Cre	eate and Send ICSRs	Create and	Send Acks	WEB Tra	der	ICSR	s Cre	ate and Sen	d Product Rep	orts	Medicinal Products	MedDRA
Reset Application Reset Section Clear Validate Send		KML ZI	RTF	Duplicate	Remove E	L	R					
⊡ ·· X	EVPRM Message											
	Products			Deser	otion	Name/	/alua		1			
	Substances			Operation	Turne	Incort (						
	Sources			Operation	) ype	insen (	0					
Ė	Organisations			LV	Type	MAH (1	<b>`</b>					
	Insert (1) - MAH (1)	- PharmeX		МАНТ	ame	Pharme	x X					
	-ATC Codes			SME S	atus	Medium	(4)					
	Pharmaceutical Forms			SME Number EMA/SME/000/00/02								
	-Routes Of Administrat	ion		MAH Sender ID								
	Attachments			Address 43 Winston Road								
	Master File Locations				City	London						
				R	gion							
				Post	code	E14 5E	U					
				Country	Code	United	Kingdom	(GB)				
				Tel Nu	mber	0207 1 <sup>-</sup>	11					
				Tel Exte	ision	222						
				Tel Country	Code	0044						
				Fax Nu	mber							
				Fax Exte	ision							
				Fax Country	Code							
				E-mail Ad	ress	Pharme	X@pharr	nex.co.uk				
				Com	ment							

# 1.2.2. Sponsor organisation

8) In the "Organisations" section of your XEVPRM, select "New Sponsor" by ticking the relevant box:

Create and Send ICSRs Create and Se	nd Acks WEB Trader	ICSRs Create and	Send Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Cl	ear Validate Send X	ML ZIP RTF E L	R		
⊡ XEVPRM Message					
Products	Num	0	Operation Type	Туре	Organisation Name
Substances	<b>☑</b> 0001	h	nsert (1)	MAH (1)	PharmeX
- Organisations	New MAH				
Insert (1) - MAH (1) - PharmeX	L New Sponsor				
-ATC Codes					
Pharmaceutical Forms					
Routes Of Administration					
Master File Locations					

The active area will display the fields relevant for a sponsor organisation entity:

Create and Send ICSRs Create and Ser	ICSR	Create and Send Product	Reports Medicinal Products MedDRA
Reset Application Reset Section Cle	ar Validate Send XML Z	IP RTF Duplicate Remove	ELR
E-XEVPRM Message			
Products	Description	Name/Value	
Substances	Operation Type	Incort (1)	
Sources	EV Codo	insert (1)	
□ Organisations	Type	Sponsor (2)	
Insert (1) - MAH (1) - PharmeX	Sponsor Name	0001001 (2)	Field is Mandatory
Insert (1) - Sponsor (2)	Sponsor Sender ID		i i i i i i i i i i i i i i i i i i i
- ATC Codes	' Address		Field is Mandatory
- Pharmaceutical Forms	City		Field is Mandatory
-Routes Of Administration	Region		
Attachments	Postcode		Field is Mandatory
Master File Locations	Country Code		Field is Mandatory
	Tel Number		
	Tel Extension		
	Tel Country Code		
	Fax Number		
	Fax Extension		
	Fax Country Code		
	E-mail Address		
	Comment		

- The "Operation type" field displays "Insert (1)" as a default. It is not possible to assign a different operation type.
- > Mandatory fields that must be populated are highlighted with the text "Field is Mandatory".
  - Please note that not all mandatory fields are highlighted this way (some fields are business rules dependent). Additional mandatory fields/fields that must contain specific value may be highlighted during the validation process (see section 1.3.
  - When information is entered in the individual mandatory fields, the text "Field is Mandatory" disappears.
  - Some of the fields contain look-up tables with pre-defined values. These values will be displayed if you press "Enter" on your keyboard.

#### 1.2.2.1. EV Code

The EV Code field is a field which will automatically display the assigned EV Code if maintenance related operation (i.e. NOT an insert) is performed. In your example, this field is blank because you are performing an insert of an entity.

#### 1.2.2.2. Туре

The value in the "Type" field is automatically set to "Sponsor" as per your selection.

#### 1.2.2.3. Sponsor Name

It is mandatory to provide information in the Sponsor Name field.

This is a free-text field.

Using your mouse, click on the area next to "Sponsor Name". The area will become highlighted in blue:



Press "Enter" on your keyboard or use the "E" ("Text Edit") button. Both actions will activate the field and allow you to write your text:

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs Create and Send Product I	Reports Medicinal Products MedDRA
Reset Application Reset Section C	ear Validate Send XML ZIP RTF Duplicate Remove	ELR
⊡-XEVPRM Message		
Substances	Description Name/Value	
Substances	Operation Type Insert (1)	
	EV Code	
En Organisations	Type Sponsor (2)	
Insert (1) Spansor (2)	Sponsor Name	Field is Mandatory
ATC Codes	Sponsor Sender ID	
Pharmacoutical Forms	Address	Field is Mandatory
Poutos Of Administration	City	Field is Mandatory
Attachmente	Region	Field in Mandatana
Master File Logetions	Postcode	Field is Mandatory
Master File Locations	Country Code	Field is Mandatory
	Tel Number	
	Tel Caunta Cada	
	For Number	
	Fax Number Fax Extension	
	Fax Country Code	
	F-mail Address	
	Comment	
L		

Type in the requested text and press "Enter" on your keyboard. The name of your sponsor will be displayed in the "Sponsor Name" field:

Create and Send ICSRs Create and Se	Acks WEB Trader ICSRs Create and Send Product	Reports Medicinal Products MedDRA
Reset Application Reset Section Cl	validate Send XML ZIP RTF Duplicate Remove	ELR
⊡ XEVPRM Message		
Products	Description Name/Value	
Substances	Operation Type Insert (1)	
Sources	EV Code	
□ Organisations	Type Sponsor (2)	
Insert (1) - Sponsor (2) - Fral ab	Sponsor Name EraLab	
ATC Codes	Sponsor Sender ID	Field is Mandetony
Pharmaceutical Forms	City	Field is Mandatory
Routes Of Administration	Region	Tield is Manualory
Attachments	Postcode	Field is Mandatory
Master File Locations	Country Code	Field is Mandatory
	Tel Number	
	Tel Extension	
	Tel Country Code	
	Fax Number	
	Fax Country Code	
	E-mail Address	
	Comment	

#### 1.2.2.4. Sponsor Sender ID

It is not mandatory to provide information in this field.

This is a free text field.

The organisation ID that corresponds to the same organisation as assigned in the EudraVigilance registration system may be provided.

Should you wish to enter the organisation ID in this field, use the same process as described in section *1.2.2.3. Sponsor Name.* 

#### 1.2.2.5. Address, City, Region and Postcode

It is mandatory to provide information in the Address, City and Postcode fields.

It is not mandatory to provide information in the Region field.

These are all free-text fields.

To enter the requested information in these fields, use the same process as described in section *1.2.2.3. Sponsor Name.* 

Description	Name/Value	
Operation Type	Insert (1)	
EV Code		
Туре	Sponsor (2)	
Sponsor Name	EraLab	
Sponsor Sender ID		
Address	Lockington Close	
City	Margate	
Region		
Postcode	MA12 4JJ	
Country Code		Field is Mandatory
Tel Number		
Tel Extension		
Tel Country Code		
Fax Number		
Fax Extension		
Fax Country Code		
E-mail Address		
Comment		

#### 1.2.2.6. Country Code

It is mandatory to provide information in this field.

The "Country Code" field is a field that will allow you to select one of the available pre-defined values.

Using your mouse, click on the area next to "Country Code". The area will become highlighted in blue:

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs Create and Send Produc	t Reports Medicinal Products MedDRA			
Reset Application Reset Section Classes	var Validate Send XML ZIP RTF Duplicate Remov	e E L R			
E-XEVPRM Message					
Products	Description Name/Value				
Sources	Operation Type Insert (1)				
□ Organisations	EV Code				
Insert (1) - MAH (1) - PharmeX	Type Sponsor (2)				
Insert (1) - Sponsor (2) - EraLab	Sponsor Name EraLab				
ATC Codes	Address Lockington Close				
Pharmaceutical Forms	City Margate				
Routes Of Administration	Region				
Attachments	Postcode MA12 4JJ				
Master File Locations	Country Code	Field is Mandatory			
	Tel Number				
	Tel Extension				
	Fax Number				
	Fax Extension				
	Fax Country Code				
	E-mail Address				
	Comment				

Press "Enter" on your keyboard, double-click on the field, or click on the "R" (Remote look-up) button. The values available for this field will be displayed:



Using your mouse, select the requested value. It will become highlighted in black:

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs	Create and Send Product Reports Medicinal Products MedDRA
		Select option
Reset Application Reset Section Cl	ear Validate Send XML ZIP	Press A - Z to find initial letter
⊡-XEVPRM Message		Press Enter to select, Escape to clear
Products	Description No	Ianzania (IZ)
Substances	Operation Type Inc	Thailand (TH)
Sources	EV Code	TIMOR-LESTE (TL)
Organisations	Type Sp	c Togo (TG)
Insert (1) - MAH (1) - Pharmex	Sponsor Name Era	a Tokelau (TK)
ATC Codes	Sponsor Sender ID	Tonga (TO)
	Address Lo	C Trinidad And Tobago (TT)
- Routes Of Administration	City Ma Pogion	Tunisia (TN)
Attachments	Postcode MA	Turkey (TR)
Master File Locations	Country Code	Turkmenistan (TM)
	Tel Number	Turks And Caicos (TC)
	Tel Extension	Tuvalu (TV)
	Tel Country Code	Uganda (UG)
	Fax Extension	Ukraine (UA)
	Fax Country Code	United Arab Emirates (AE)
	E-mail Address	United Kingdom (GB)
	Comment	United States (US)

Once you click on the selected value, it will be displayed in the "Country Code" field:

Create and Send ICSRs Create and Se	and Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedD	RA
Reset Application Reset Section Cl	lear Validate Send XML ZIP RTF Duplicate Remove E L R	
⊡ XEVPRM Message		
Products	Description Name/Value	
Substances		
Sources	EV Code	
- Organisations	Type Sponsor (2)	
Insert (1) - MAH (1) - PharmeX	Sponsor Name EraLab	
Insert (1) - Sponsor (2) - EraLab	Sponsor Sender ID	
-ATC Codes	Address Lockington Close	
Pharmaceutical Forms	City Margate	
-Routes Of Administration	Region	
Attachments	Postcode MA12 4JJ	
Master File Locations	Country Code United Kingdom (GB)	
	Tel Number	
	l el Extension	
	Tel Country Code	
	Fax Number	
	Fax Country Code	
	F-mail Address	
	Comment	

# 1.2.2.7. Tel Number, Extension, Country Code, Fax Number, Fax Extension, Fax Country Code and E-mail address

It is not mandatory to provide information in these fields.

These are free-text fields.

Should you wish to enter the requested information in these fields, use the same process as described in section *1.2.2.3. Sponsor Name.* 

#### 1.2.2.8. Comment

This is a free- text field, in which information can be entered using the same process as described in section *1.2.2.3. Sponsor Name.* 

As per the applicable business rules, the "Comment" field must contain the reason for nullification if operation type 'Nullification (4)' is used on the sponsor entity.

No information should be entered in this field in this particular case since you are performing an 'Insert (1)'.

You have now populated the fields for a sponsor organisation entity "EraLab":

Create and Send ICSRs Create and S	Send Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section	Clear Validate Send XML ZIP RTF Duplicate Remove E L R
□ XEVPRM Message	
Products	Description Name/Value
Substances	
Sources	EV Code
Organisations	Type Sponsor (2)
Insert (1) - MAH (1) - Pharmex	Sponsor Name EraLab
Insert (1) - Sponsor (2) - EraLab	Sponsor Sender ID
AIC Codes	Address Lockington Close
Pharmaceutical Forms	City Margate
Attachmente	Region Region
Master File Logations	Postcode MA12 4JJ
Master File Locations	Tal Number
	Tal Evansion
	Tel Country Code
	Fax Number
	Fax Extension
	Fax Country Code
	E-mail Address EraLab@eralab.com
	Comment

## 1.3. Validate and send an XEVPRM

1) Validate your XEVPRM by clicking with your mouse on the "Validate" button.

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create ar	nd Send Product Repo	orts Medicinal Products	MedDRA
Reset Application R	eset Section Clear R	eplicate Validate	Send	XML ZIP	RTF Duplicate F	Remove E L R	

New window will be displayed on your screen, showing the result of your validation:

If your XEVPRM contains any technical errors (i.e. mandatory information is missing), an error message will be displayed on your screen:



The section, where these errors occurred will be highlighted in red and/or the fields where information is missing will contain the text "Field is Mandatory":



Once you click on "OK" in the error message or click on the section highlighted in red, the application will direct you to the first error. You should enter/correct the required information and validate the XEVPRM again.

If your XEVPRM has been created correctly, the new window will display the text "Validate OK", which means that no errors were reported:

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs C	Create and Send Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Cl	ear Validate Send XML ZIP R	TF E L R		
E XEVPRM Message				
Products	Description Name	/Value		
- Substances - Sources Dorganisations - Insert (1) - MAH (1) - PharmeX - Insert (1) - Sponsor (2) - EraLab - ATC Codes - Pharmaceutical Forms - Routes Of Administration - Attachments - Master File Locations	Message Number Produc Substa Source Organi ATC C Pharm Routes Attach Maste	MAH and sponsor cts ances es isations Codes acceutical Forms s Of Administration iments er File Locations	m webp 💌 Validate OK	

You can dismiss the message by clicking on "OK".

2) Save the XEVPRM for your reference by clicking on the relevant button:

Create and Send ICSRs		s Cre	Create and Send Acks			WEB Trader ICS			Crea	ite ar	d Sen	d Product Reports	Medicinal Products	MedDRA
	Reset Application	Reset S	Section	Clear	Validate	Send	XML	ZIP	RTF	Е	L R			

3) Send the XEVPRM by clicking on the "Send" button. The below message will be displayed on your screen:

Create and Send ICSRs Create and Ser	nd Acks WEB Trader ICSF	Create and Send Product Repo	orts Medicinal Products	MedDRA				
Reset Application Reset Section Cle	ear Validate Send XML Z	IP RTF E L R						
E-XEVPRM Message								
Products	Description	Description Name/Value						
Substances	Message Number	Insert MAH and sponsor						
		Products						
Incort (1) MAH (1) PharmaX		Substances						
Insert (1) Sponsor (2) Frai ab		Sources						
ATC Codes		Organisations						
Dhamman tine Farma		ATC Codes						
Pharmaceutical Forms		Pharmaceutical Forms						
Routes Of Administration		Routes Of Administration						
Attachments		Attachments						
Master File Locations		Master File Locations						

The below message will confirm that your XEVPRM has been sent:

С	reate and Send ICSRs	Create and Se	nd Acks	WEB Trader	ICSRs	Create and Send Product	Reports	Medicinal Products	MedDRA	
	Reset Application Re	eset Section Cle	ear Val	idate Send X	ML ZIP	RTF E L R				
	XEVPRM Message									
	Products			Desc	ription N	ame/Value				
	Substances			Message N	lumber In:	sert MAH and sponsor				
	Organications			, in the second s	Pr	oducts				
	Insert (1) - MΔH (1) -			Su	ubstances					
	Insert (1) - Sponsor (			So	ources					
	ATC Codes					ganisations				
	-Pharmaceutical Forms				PI	narmaceutical Forms	Message	from webpage		x
	-Routes Of Administration	on			R	outes Of Administration				
	Attachments				At	tachments		6		
	Master File Locations				M	aster File Locations		Send Operation Complet	ted	
								If You want to View the F	ile(s) Sent Click	[OK]
								0	к	Cancel

If you want to view/save your file, click on "OK".

The below message will be displayed, enabling you to save your XEVPRM file on your computer:

🏉 https://evtest.e	ma.europa.eu/X/?XI=6 - Windows Internet Explorer		• <mark>•</mark>	3
Summar	у			*
Temporary	Click <u>here</u> for the file			
(for				
Export)	Name: dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27	+10.	58.16	-
	EVPRM Zipped Message			
	Message Number: Insert MAH and sponsor			
To the	Name:			
Outbox				
	EVPRM Zipped Message			
	Message Number: Insert MAH and sponsor			

## 1.4. Retrieve the XEVPRM Acknowledgement (XEVPRM ACK)

1) Go to the "Web Trader" section

Create and Send ICSRs		s Create and	Send Acks	WEB Trader ICSRs		Create and Send Product Reports	Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear Lo	al Import	Create Ack 👻			

2) Click on "Inbox" (or "Archived Inbox" under "Archive", depending on when you decide to retrieve your XEVPRM ACK).

The application will appear "frozen" for a second or two:

Create and Send ICSRs Create a		Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA				
	Reset Application     Reset Section     Clear     Remote Import     Create Ack										
Γ	Imported Messages (-)										
	Inbox Outbox										
	Archive										

After a few seconds, the active area will display XEVPRM ACKs sent to your organisation's ID (the first message will be automatically highlighted in blue):

Create and Send ICSRs Create and Se	nd Acks WEB Trader ICSRs Create and Send Product Reports Medicinal Products MedDRA										
Reset Application Reset Section C	ear Remote Import Create Ack 0										
Imported Messages (-)											
Outbox	Num Name	Num/Count	Date	Size							
Due to Event Files	0001 ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/13	2014/08/27 11:02.41	00000037							
Auchine Auchine	0002 ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/13	2014/08/22 12:35.56	00000050							
	0003 ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/13	2014/07/30 13:43.28	00000031							
	0004 ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/13	2014/07/30 11:20.27	00000031							
	0005 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-QPPV update-2014-07-14+15.01.39-01.xml	0/13	2014/07/17 14:52.39	0000030							
	0006 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_ProductX_vb-2014-07-02+14.59.32-01.xml	0/13	2014/07/02 15:03.57	0000037							
	0007 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Goshi 25 Capsules_vb-2014-07-02+11.15.28-01.xml	0/13	2014/07/02 11:19.56	00000044							
	0008 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Update_ORG4187_vb-2014-07-02+11.07.11-01.xml	0/13	2014/07/02 11:11.56	0000030							
	0009 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Nikko tablets_vb-2014-07-02+10.03.28-01.xml	0/13	2014/07/02 10:07.55	00000044							
	0010 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_DrugVero_vb-2014-07-02+10.01.59-01.xml	0/13	2014/07/02 10:05.55	00000043							
	0011 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-DrugVero_insert_vb-2014-06-26+13.17.33-01.xml	0/13	2014/06/26 13:22.16	00000049							
	0012 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Nikko tablets_insert_vb-2014-06-26+13.01.53-01.xml	0/13	2014/06/26 13:07.15	00000049							
	0013 ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Test product_insert_vb-2014-06-26+12.04.10-01.xml	0/13	2014/06/26 12:09.14	0000038							

To view the ACK name in full, expand the section by placing your cursor on the separator line between "Name" and "Num/Count", click and drag towards the right until the full name is visible:

Num	Name	Jum/Count	Date	Size
0001	ack dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert	0/14	2014/08/27 14:18.43	00000030
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert	0/14	2014/08/27 11:02.41	00000037
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert	0/14	2014/08/22 12:35.56	00000050
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert	0/14	2014/07/30 13:43.28	00000031
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert	0/14	2014/07/30 11:20.27	00000031

Num	Name	Num/Count	Date	Size
0001	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13,21-01.xml	0/14	2014/08/27 14:18.43	0000030
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/14	2014/08/27 11:02.41	00000037
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/14	2014/08/22 12:35.56	00000050
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/14	2014/07/30 13:43.28	00000031
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/14	2014/07/30 11:20.27	00000031

3) Based on the XEVPRM number, which you assigned to your message, find the XEVPRM ACK.

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Step-by-Step Guide EMA/467742/2014

Click on the relevant row with your mouse (the message will be highlighted in blue):

Num	Name
0001	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml

Press "Enter" on your keyboard or double-click with your mouse and the XML of the XEVPRM ACK will be displayed on your screen, showing the operation result and the assigned EVCode(s):

🏉 dcmtes	tmahtt (DCMTESTMAH) @ Human Production V. 7.9.1 - Windows Internet Explorer	The Paperson Named
00	→ Image: State of the stat	
File Ed	🍘 https://evtest.ema.europa.eu/X/Export.asp?F681E859-CB9D-4B12-AC80-2AB4D0C3A2DD - Windows Internet Explorer	
🔶 Favor	File     Edit     View     Favorites     Tools     Help       X	
File Ed	https://evtest.ema.europa.eu/X/Export.asp?f681E859-C890-4812-AC80-2A84D0C3A2DD - Windows Internet Explorer          File       Edit       View Favorites       Tools       Help       x @ Convert < @ Select <messagedate> 20140827105959       <messagedate> 20140827105959           <messagedate> 20140827105959       <messagedate> 20140827105959           <messageadeate> 20140827105959       <messageadeate> 20140827105959           <messageadeate> 20140827105959       <messageadeate> 20140827105959           <messageadeate> 20140827105959       <messagesageadeate> 20140827105959       <messageadeate> 20140827105959          <messageadate> 2014/originalmessagedateformat &gt; 204       <messagedate> 2014/originalmessagedate &gt; 2014/originalmess</messagedate></messageadate></messageadeate></messagesageadeate></messageadeate></messageadeate></messageadeate></messageadeate></messageadeate></messagedate></messagedate></messagedate></messagedate>	ts MedDRA 58.16-01.xml blets-2014-08-22+12.31.28-01.xml 39.50-01.xml 01.xml +11.15.28-01.xml 11-01.xml 3.28-01.xml 01.xml 01.xml 01.xml 01.xml 01.xml 01.xml 01.xml
	<pre>- <reportacknowledgment></reportacknowledgment></pre>	1.53-01.xml 10-01.xml

The insert of your MAH and sponsor organisations was successful.

4) You can save the XML file of the XEVPRM ACK on your computer by going to "File" and selecting "Save As":

🏉 ht	tps://e	/test.em	a.europa.eu	/X/Expo	rt.asp?3	B9EAF89-B63A-4B47-B960-349CC88DD2A5 - Windows Internet Explo	rer				X		
File	Edit	View	Favorites	Tools	Help		х	Conve	rt 🔻	📑 Sele	ect		
1	New T	ab		Ct	trl+T						*		
	Duplic	ate Tab		Ct	trl+K	JTF-16" ?>							
	New V	Vindow		Cti	rl+N	"W.W3.0FG/2001/XMLSCNema-INSTance" >="http://eudravigilance.ema.europa.eu/schema/ackveympd.vs/							
	New S	ession				on= http://euuravigilance.eina.europa.eu/sch	eme		viii	paixsa	1		
	Open.			Ct	rl+O	nessagetype>							
	Edit with Microsoft Word												
	Save			Ct	trl+S								
	Save	10				28703-ACK							
	Close	Tala		C+-	4.14/	/TEST							
	Close	Tab		Ctr	1+ VV	messagedateformat >					=		
1	Page S	Setup				05959							
	Print			Ct	rl+P	obsos (messageauce)							
	Print P	review.											
	Send				+	-M-128703							
	Impor	t and Ex	port			sert MAH and sponsor							
	Brone	tion				ntifier>DCMTESTMAH <td>ntifie</td> <td>er&gt;</td> <td></td> <td></td> <td></td>	ntifie	er>					
	Proper	orr				entifier>EVTEST <td>&gt;</td> <td></td> <td></td> <td></td> <td></td>	>						
	WORK	Offline				at>204							
	Exit					14082/105816							
I —			smission	acknow	ment	nentcode> <b>01</b>							
	- <	report	acknowle	damer	nt>	-							
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You have now successfully retrieved the XEVPRM Acknowledgement.