

5 April 2018 EMA/543104/2014 Information Management

eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) Step-by-Step guide

Maintenance operations: Update of an authorised medicinal product (AMP) entity in the XEVMPD

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555 Send a question via our website www.ema.europa.eu/contact



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Table of contents

1.1. Exa	ample specifications	. 3
1.2. Re	trieve the AMP entity	.4
1.3. Cre	eate an XEVPRM	.8
1.4. Va	lidate and send an XEVPRM	14
1.5. Re	trieve the XEVPRM Acknowledgement (XEVPRM ACK)	18

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

1.1. Example specifications

For the purpose of this step-by-step exercise, you will be updating your previously submitted AMP with the name "Luna 21 PharmaL contraceptive tablets".

The following information needs to be amended using operation type 'Update (2)':

- The authorisation procedure should be changed from "National Procedure" to " Mutual Recognition Procedure";
- The MRP number "SE/H/0001/002" must be specified in the "MRP/DCP/EMEA number" field.

1.2. Retrieve the AMP entity

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 Vigilar Human Restricted	nce:		
EV Services	Pharmaceutical Industries	and Commercial Sponsors	
► EVWEB ► xEVMPD Export	Please select the initial of the A B C D E F G H I J K	Organisation ID: M N O P Q R S T U V W Y Z 0-9	
EV Post	Regulators		
P LV POSt	Organisation Name	Organisation ID	Country
EV Registered		- The second	-
Partners			
Manage your profile			
▶ QPPV List			
Organisations List			
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 Producti
Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA	
Reset Application Re	set Section Clear						
				1			

- Go to the "Medicinal Products" section and using the simple or advanced query, retrieve the specific product entry. Search for "Luna 21*"
 - Please refer to the <u>eXtended EudraVigilance Medicinal Product Dictionary</u> (XEVMPD) Data-Entry Tool (EVWEB) User Manual, sections 4.2. Simple queries in the XEVMPD and 4.3. Advanced Queries in XEVMPD for information how to perform simple and advanced queries.

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and	Send Product Reports	Medicinal Products	MedDRA		
Reset Application Re	eset Section Clear 🗘								
Authorised Medicinal Produ	Authorised Medicinal Products								
Development Medicinal Pro	ducts	Num	EV	Code	Full Presentation Name			Short Name	
Approved Substances		0001	PRE	0112205	Luna 21 PharmaL contrac	ceptive tablets		Luna 21	
Development Substances		_							
Sources									
MAHs									
Sponsors									
ATC Codes									
-Routes of Administration									
- Pharmaceutical Forms									
-Master File Locations									
Attachments									
-Abstract Compositions									
Queries									

3) Select the medicinal product by ticking the relevant box in the active area:

Create and Send ICSRs Create and Send Acks W	EB Trader	ICSRs	Create and	Send Product Reports	Medicinal Products	MedDRA	
Reset Application Reset Section Clear	Ø						
Authorised Medicinal Products	Luna 21*	:					
Development Medicinal Products	Num	EV (Code	Full Presentation Name			Short Name
Development Substances	0001	PRD	112205	Luna 21 PharmaL contrac	ceptive tablets		Luna 21
Sources							
MAHs							
Sponsors							
ATC Codes							
Routes of Administration							
Pharmaceutical Forms							
Master File Locations							
Attachments							
Abstract Compositions							
l ⊡ Queries							

The medicinal product is now displayed in the tree-view area:

Create and Send ICSRs Create and Send Acks WEB Trader	ICSRs	Create and Sen	d Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Clear					
Authorised Medicinal Products		Luna 21*			
Current (1) - PRD112205 - Luna 21 PharmaL contraceptive tablets		Num	EV Code	Full Presentation Name	l.
- Development inedicinal Products		0001	PRD112205	Luna 21 PharmaL contr	aceptive tablets
- Development Substances					
Sources					
MAHs					
Sponsors					
ATC Codes					
Routes of Administration					
Pharmaceutical Forms					
Master File Locations					
Attachments					
Abstract Compositions					
⊡_Queries					

4) Click on the product's name in the tree-view area:

P Authorised Medicinal Products
Current (1) - PRD112205 - Luna 21 PharmaL contraceptive tablets
- Development Medicinal Products
Approved Substances
Development Substances
Sources
MAHs
Sponsors
ATC Codes
Routes of Administration
Pharmaceutical Forms
Master File Locations
Attachments
Abstract Compositions

The product details are displayed in the active area and the operation type buttons applicable for this AMP are also visible:

Create and Send ICSRs Create and Send Acks WEB Trader	ICSRs Create and Send Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear XML RTF Update	• Other Operations -
P Authorised Medicinal Products	Luna 21*
Current (1) - PRD112205 - Luna 21 PharmaL contraceptive tablets	Description NameAlalue
- Development Medicinal Products	Description trainer and Observations the
-Approved Substances	
-Development Substances	NullFed No
-Sources	EV Code PRD112205
MAHs	Category
- Sponsors	PhV enquiry email pharmacovigilance@pharmaL.com
-ATC Codes	PhV enguiry Phone 0044 123 456 7890
-Routes of Administration	Sender Local Code
-Pharmaceutical Forms	Info Date
-Master File Locations	Authorisation Country Code United Kingdom (GB)
-Attachments	Authorsation Procedure EU authorsation procedures - National Procedure (4)
-Abstract Compositions	Authorisation Status Valid (1)
⊕ Quenes	Autorisation vumber 1234/5676
	Managara and a set of the set of
	EU Number
	Legal Basis Full application (Article 8(3) of Directive No 2001/83/EC) (1)
	Orphan Drug No (2)
	Additional Monitoring No (2)
	Invalidated Date
	Full Presentation Name Luna 21 PharmaL contraceptive tablets
	Product Short Name Luna 21
	Product INN/Common Name
	Product Company Name PharmaL
	Product strength twane Doduct strength and COMTDACEDTIVE TABLETS
	Product Dispringing DVC/ALLIMINI IN FOIL BUISTED STDIPS WITH OD WITHOUT A CADD WALLET IN CADDBOADD CADTON, CONTAINING 3 X 21 TABLETS.
	Comment
	MAH
	Master File Location
	QPPV
	Medicinal Product Types (·)
	Authorised Pharmaceutical Forms (-)
	Pharmaceutical Products (1)

5) Click on operation type button "Update":

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create and Se	end Prod	uct Reports	Medicinal Products	MedDRA
Reset Application R	eset Section Clear XM	L RTF Updat	e Other	Operations 👻				
- Authorised Medicinal Prod	ucts		Luna 2	1*				
	95 - Luna 21 PharmaL contrac	eptive tablets		Dec	cription	NameA/alue		
- Development Medicinal Pro	oducts			Des	scription	Name/value		
Approved Substances				U	лескеа	NO		
Development Substances					Cleaned	No		
Sources				_	Nullified	No		
MAHe				EV Code PRD112205				
0				Category				
Sponsors				PhV enquiry email pharmacovigilance@pharmaL.com				
AIC Codes				PhV enquiry Phone 0044 123 456 7890				
Routes of Administration			Sender Local Code					
-Pharmaceutical Forms				In	nfo Date			
Master File Locations			Authorisation Country Code United Kingdom (GB)					
Attachments				Authorisation Pro	ocedure	EU authorisatio	on procedures - National	Procedure (4)
Abstract Compositions				Authorisation Status Valid (1)				
H-Queries			Authorisation Number 1234/5678					
			A	uthorisation/Renew	val Date	01/10/2005		
				MRP/DCP/EMEA	Number			

The AMP entity will be moved from the "Medicinal Products" section to the "Create and Send Product Reports" section:

Create and Send ICSRs	Create and Send Acks	WEB Trader	ICSRs	Create a	and Send Product Reports	Medicinal Products	MedDRA	
Reset Application R	eset Section Clear Va	lidate Send X	ML ZIP	RTF E	LR			
□ XEVPRM Message					Luna 21*			
⊨ Products					Descri	ntion Name/Value		
Update (2) - Authori	sed (2) - PRD112205 - Luna 2	21 PharmaL contra	aceptive tab	lets	Message Nu	mber	Field i	s Mandatory
Medicinal Produc	ct Types (1)	44 (7) (10	(EQ) N	700/0004		Products		,
Conditional M	arketing Authorisation (Article	e 14 (7) of Regulat	ion (EC) No	0 726/2004		Substances		
	naceutical Forms (1)					Sources		
- Pharmaceutical	Products (1)					Organisations		
						AIC Codes Decreaseutical Ec		
Drug ATCs (1)						Pharmaceutical Po	stration	
Drug Indications	(2)					Attachments	in anom	
-Previous EV Cod	les (-)					Master File Location	ons	
Product Attachm	ients (1)							
Substances								
Sources								
Organisations	- Organisations							
ATC Codes								
Pharmaceutical Forms								
Routes Of Administration	on							
Attachments Meeter File Leastione								
Invision File Locations								

1.3. Create an XEVPRM

 By clicking on the area next to the "Message Number" (the area is highlighted in blue)with your mouse, clicking on the "E" (Text Edit) button or pressing "Enter" on your keyboard, the field will 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 Reports	Medicinal Products Me	dDRA
Reset Application Reset Section Clear Validate Send XML ZIP RTF E	LR		
□ XEVPRM Message	Luna 21*		
⊡ Products	Descripti	ion Name/Value	
Update (2) - Authorised (2) - PRD112205 - Luna 21 PharmaL contraceptive tablets	Message Numb	ber	Field is Mandatory
Medicinal Product Types (1) Organization Anthony strength (Article 14 (7) of Deputation (EQ) No. 700(2004)	5	Products	,
Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004		Substances	
		Sources	
Deciritical Products (1)		Organisations	
		AIC Codes	
T-Drug ATCs (1)		Pharmaceutical Forms Routes Of Administratio	n
⊕ Drug Indications (2)		Attachments	
Previous EV Codes (-)		Master File Locations	
Substances			
Sources			
Organisations			
ATC Codes			
Pharmaceutical Forms			
Routes Of Administration			
Attachments			
Master File Locations			

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create a	and Send Product Reports Medicinal Products MedDRA								
Reset Application Reset Section Clear Validate Send XML ZIP RTF E L R									
⊡-XEVPRM Message	Luna 21*								
	Description Name/Value								
Update (2) - Authorised (2) - PRD112205 - Luna 21 PharmaL contraceptive tablets	Message Number								
☐ Medicinal Product Types (1)	Products								
Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004	Substances								
Authorised Pharmaceutical Forms (1)	Sources								
	Organisations								
	ATC Codes								
	Pharmaceutical Forms								
E Drug Indications (2)	Attachments								
Previous EV Codes (-)	Master File Locations								
Product Attachments (1)									
Substances									
Sources									
- Organisations									
ATC Codes									
Pharmaceutical Forms									
Routes Of Administration									
Attachments									
Master ⊢ile Locations									

2) Enter the name of your XEVPRM:

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create	and Send Product Reports	Medicinal Products	MedDRA
Reset Application Reset Section Clear Validate Send XML ZIP RTF E	LR		
E-XEVPRM Message	Luna 21*		
Products	Descrip	otion Name/Value	
Update (2) - Authorised (2) - PRD112205 - Luna 21 PharmaL contraceptive tablets	Message Nur	nber Update PRD11220)5
Conditional Marketing Authorization (Article 14 (7) of Population (EC) No 726/2004	-	Products	
Conditional Marketing Authonisation (Article 14 (7) or Regulation (EC) No 720/2004 Authorised Pharmaceutical Forms (1)		Substances	
		Sources	
□-Pharmaceutical Products (1)		Organisations	
⊡-TABLET		Pharmaceutical Ec	rms
⊕ Drug ATCs (1)		Routes Of Adminis	tration
Drug Indications (2)		Attachments	
Previous EV Codes (-)		Master File Location	ons
Substances			
Sources			
Organisations			
AIC Codes			
- Pharmaceutical Forms			
Attack of Administration			
Menter File Legations			
···· Waster File Locations			

3) Click on the product's name in the tree-view area:

⊡-XEVPRM Message
products
Update (2) - Authorised (2) - PRD112205 - Luna 21 PharmaL contraceptive tablets
Generation Product Types (1)
Conditional Marketing Authorisation (Article 14 (7) of Regulation (EC) No 726/2004) (4)
Authorised Pharmaceutical Forms (1)
TABLET
⊡ Pharmaceutical Products (1)
⊞ Drug ATCs (1)
⊡ Drug Indications (2)
Previous EV Codes (-)
Product Attachments (1)
Substances
Sources
Organisations
ATC Codes
Pharmaceutical Forms
-Routes Of Administration
Attachments
Master File Locations

The active area will display the fields of your AMP:

The "Operation type" field displays "Update (2)" as a default. It is not possible to assign a different operation type.



4) As per our specific example, click on the area next to the "Authorisation Procedure". The value of this field will be highlighted in blue:

Description	Name/Value
Operation Type	Update (2)
Туре	Authorised (2)
EV Code	PRD112205
MAH	PHARMAL LTD
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7858 - United Kingdom (GB) - Portsmouth
PhV enquiry email	pharmacovigilance@pharmaL.com
PhV enquiry Phone	0044 123 456 7890
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - National Procedure (4)

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

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:

Select option
Press A - Z to find initial letter Press Enter to select, Escape to clear
EU authorisation procedures - Centralised Procedure (1)
EU authorisation procedures - Mutual Recognition Procedure (3)
EU authorisation procedures - Decentralised Procedure (7)
EU authorisation procedures - National Procedure (4)
Non EU authorisation procedure (5)
EU authorisation procedures - Traditional use registration for herbal medicinal products (11)
EU authorisation procedures - Simplified registration procedure for homeopathic medicinal products (12)

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

Remove ELLR
19.21
Decembra News Afebra
Description Name/Value Operation Type Update (2) EV Code PRO112205 MAH PH4/8/ALL ITD OPPV Jehn Smith (DCMTESTMAH) Master File Location MFL7853 - United Kingdom (08) - Potsmouth PRV enginy Phone 0044 123 456 7890 Sender Local Code Info Date Authorisation Franz-ongliance@pharmaL.com PNV enginy Phone 0044 123 456 7890 Sender Local Code Info Date Authorisation Status Value Info Date Authorisation Status Value Info Date Authorisation Number 1234/5678 Authorisation Number 1234/578 Authorisation Number 12

5) As per our specific example, click on the area next to "MRP/DCP/EMEA Number". The value of this field will be highlighted in blue:

Description	Name/Value
Operation Type	Update (2)
Туре	Authorised (2)
EV Code	PRD112205
MAH	PHARMAL LTD
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7858 - United Kingdom (GB) - Portsmouth
PhV enquiry email	pharmacovigilance@pharmaL.com
PhV enquiry Phone	0044 123 456 7890
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure (3)
Authorisation Status	Valid (1)
Authorisation Number	1234/5678
Authorisation/Renewal Date	01/10/2005
MRP/DCP/EMEA Number	

The "MRP/DCP/EMEA Number" is a free-text field.

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:

Description	Name/Value
Operation Type	Update (2)
Туре	Authorised (2)
EV Code	PRD112205
MAH	PHARMAL LTD
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7858 - United Kingdom (GB) - Portsmouth
PhV enquiry email	pharmacovigilance@pharmaL.com
PhV enquiry Phone	0044 123 456 7890
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure (3)
Authorisation Status	Valid (1)
Authorisation Number	1234/5678
Authorisation/Renewal Date	01/10/2005
MRP/DCP/EMEA Number	

Type in the requested text and press "Enter" on your keyboard. The text will be displayed in the "MRP/DCP/EMEA Number" field:

Description	Name/Value
Operation Type	Update (2)
Туре	Authorised (2)
EV Code	PRD112205
MAH	PHARMAL LTD
QPPV	John Smith (DCMTESTMAH)
Master File Location	MFL7858 - United Kingdom (GB) - Portsmouth
PhV enquiry email	pharmacovigilance@pharmaL.com
PhV enquiry Phone	0044 123 456 7890
Sender Local Code	
Info Date	
Authorisation Country Code	United Kingdom (GB)
Authorisation Procedure	EU authorisation procedures - Mutual Recognition Procedure (3)
Authorisation Status	Valid (1)
Authorisation Number	1234/5678
Authorisation/Renewal Date	01/10/2005
MRP/DCP/EMEA Number	SE/H/0001/002

You have now amended the fields as per our example specifications.

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create and S	end Product Reports Medicinal Products MedDRA
Reset Application Reset Section Clear Replicate Validate Send XML ZIP R	FF Remove E L R
XEVPRM Message	Luna 21*
Products	Description Name/Value
Bupdare (2) - Authonsed (2) - PRO112205 - Luna 21 Pharmal, contraceptive tablets Bedicinal Product Types (1) Conductional Marketing Authonsation (Article 14 (7) of Regulation (EC) No 725/2004) (4) Authonse Pharmaceutical Forms (1) TABLET Boug ATOs (1) Broud Marketing Power and Products (1) Broud Marketing Prevous EV Codes (-) Prevous EV Codes (-) Broud Attachments (1) Sources Cognisations ATC Codes Pharmaceutical Forms Routes Of Atministration Attachments Master File Locations	Description Name/Nales Operation Type Authorsed (2) EV Code PR0112205 MAH PHARMAL LTD OPPY Dismitrin (DCMTESTMAH) Master File Location ME17858 Dismitrin (DCMTESTMAH) Master File Location PNV enginy remain Sparmacolgiance@glammal.com PNV enginy remain Glammacolgiance@glammal.com PNV enginy remain Glum 2456789 Authorisation Status Valid (1) Authorisation Reveal Date Valid (1)

1.4. Validate and send an XEVPRM

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

Create and Send ICSRs	Create and	WEB *	Trader	ICSRs Create and Send Product Reports					Medicin	Medicinal Products		
Reset Application Re	eset Section	Clear	eplicate	Validate	Send	XML	ZIP	RTF	Duplicate Remo	ve E L	R	

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

Create and Send ICSRs	Create and Send A	cks WEB	Trader	ICSRs	Cre	ate ar	d Sen	d Product F	Reports	Medie	icinal Products	MedDRA		
Reset Application R	eset Section Clear	Replicate	Validate	Send	XML	ZIP	RTF	Remove	EL	R				
								.una 21*						
Products							Ē							
Update (2) - Authorised (2) - PRD112205 - Luna 21 PharmaL contraceptive tablets										Descript	tion Name/Valu	e		
Medicinal Produce	t Types (1)								Ope	ration Ty	ype Update (2)	(0)		
Conditional M	arketing Authorisation (Article 14 (7)	of Regulation	on (EC) N	o 726/2	004) (4	4)			EVC	ode DDD112200	(2)		
Authorised Phar	maceutical Forms (1)									EVCO	INTERPRETER			
TABLET										OP	PV John Smith	(DCMTESTMA	AH)	
Pharmaceutical I	Products (1)								Master F	ile Loo-	MEL 7000	I laike at 12 in a star		
									PhV er	nquiry N	Message from web	opage	×	J
⊡ Drug ATCs (1)									PhV end	quiry F				1
Drug Indications	(2)								Sender	Local	Nalidat	to Epiled		
Previous EV Cod	es (-)									Info		teralleu		
Product Attachm	ents (1)							Author	isation Co	ountry	1 Error	(s) present		December (2)
Luna 21_SmF	C (EN)							Aut	Authorics	1 Proc				Procedure (5)
Substances									Authoricat	ion Nu	First er	ror(s):	Validity declaration	
Organisations								Authori	isation/Re	newal	Field	must have a spe	cified value	
ATC Codes								MRP	DCP/EM	EA Nu				
Pharmaceutical Forms									1	EU Nu	Press (OK to go to the F	irst error	
	nn								I	Legal I				EC) (1)
Attachments									C	Orphan				
Master File Locations									Additional	Moni		ОК	Cancel	
								E.	Inval	Idated				J
								FU	Droduct 9	Short Na	ame Luna 21	annal contract	eptive tablets	
								Product	INN/Com	mon Na	ame			
								Pro	duct Com	pany Na	ame PharmaL			
								Pro	oduct Stre	ength Na	ame			
									Product I	Form Na	ame CONTRACE	EPTIVE TABLE	TS	
									Package	Descript	tion PVC/ALUM	IINIUM FOIL BL	ISTER STRIPS WITH C	R WITHOUT A CARD
										Comm	nent			

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"/"Field must have a specific value"/"Field is Mandatory Optional".

Click on "OK" and the application will direct you to the first error. Enter/correct the required information:

Create and Send ICSR	Create and	I Send A	cks WE	B Trade	r IC	SRs	Crea	ite and S	nd Product Reports Medicinal Products MedDRA	
Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplica	Remove E L R	
XEVPRM Message									Luna 21*	
Products								Description Name/Value		
⊡ Update (2) - Auth	prised (2) - PRD1	12205 - L	una 21 Pha	rmaL con	tracept	ive tab	lets		Product Attachment Luna 21 SmPC (EN)	
Medicinal Pro	luct Types (1)			(0)			700/00		Validity declaration Field must have a specified	value
Conditional	Marketing Autho	risation (A	Article 14 (7) of Regu	lation (EC) NO	/26/20	JU4) (4)		
	armaceutical For	ms (1)								
- Pharmaceutic	I Products (1)									
+ TABLET										
⊕ Drug ATCs (1)										
Drug Indication	is (2)									
-Previous EV C	odes (-)									
Product Attac	ments (1)									
Luna 21_S	nPC (EN)									
Substances										
Organisations										
ATC Codes										
Pharmaceutical Form	15									
-Routes Of Administr	ation									
Attachments										
Master File Location	6									

Since we are performing an update of an AMP, as per the applicable business rules, we must specify that the referenced PPI attachment is still valid.

The "Validity declaration" 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 "Validity declaration". The area will become highlighted in blue:

Description	Name/Value
Product Attachment Validity declaration	Luna 21_SmPC (EN)

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:

Description	Name/Value	
Product Attachment Validity declaration	Luna 21_SmPC (EN)	
	Select optio	n
	Press A - Z to find ini Press Enter to select, Esc	tial letter cape to clear
	Valid (1)	

Using your mouse, select the requested value. Once you click on the selected value, it will be displayed in the "Validity declaration" field:

Cre	eate and Send ICSR	s Create and	Send A	cks WE	B Trade	r IC	SRs	Crea	ite and Se	end Product Reports Medicinal Products MedDRA
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	e Remove E L R
⊡ X	EVPRM Message									Luna 21*
Ē	Products									Description Name/Value
	Update (2) - Auth	orised (2) - PRD1	12205 - L	una 21 Pha	rmaL cor	tracept	ive tab	lets		Product Attachment Luna 21 SmPC (EN)
	Medicinal Pro	duct Types (1)		A		1-1		700100	0.0.70	Validity declaration Valid (1)
	- Authorized Pk	armacoutical For	nsation (A	Article 14 (7) or Regu	iation (i) / 20/20)04) (4)	
	TABLET	annaceuticai i oi	ilis (1)							
	⊡ Pharmaceutic	al Products (1)								
	Drug ATCs (1)								
	Drug Indicatio	ns (2)								
	Previous EV (Codes (-)								
	Product Attac	hments (1)								
	Euna 21_5	MPC (EN)								
	Sources									
	Organisations									
	ATC Codes									
	-Pharmaceutical For	ms								
	Routes Of Administ	ation								
	Attachments									
	Master File Location	IS								

Validate the XEVPRM again.

Create and Send ICSRs Create and Send Acks WEB Trader ICSRs Create							ite and S	Send	d Product Reports	Medicinal Products	MedDRA		
	Reset Application R	eset Section	Clear	/alidate	Send	XML	ZIP	RTF	Duplica	ate	Remove E L	R	
⊡ · XE	XEVPRM Message										una 21*		
ļ	Products									Г		Description Name/Value	<u></u>
	Update (2) - Authori	sed (2) - PRD1	12205 - Luna	a 21 Pha	rmaL con	tracept	ive tab	lets			Product A	Attachment Luna 21 Sn	PC (EN)
	Medicinal Produce	ct Types (1)									Validity	declaration Valid (1)	
	Conditional M	larketing Autho	risation (Arti	cle 14 (7) of Regu	lation (EC) No	0 /26/20)04) (4)		,		
	Authorised Phari	maceutical Fori	ms (1)										
	Dearmacoutical	Products (1)											
		roducts (1)											
	⊕ Drug ATCs (1)										Messag	ge from webp	
	Drug Indications	(2)											
	Previous EV Cod	les (-)											
	Product Attachm	nents (1)										Validate OK	
	Luna 21_SmF	PC (EN)											
	Substances												
	Sources											ОК	
	Organisations												
	AIC Codes												
	Pharmaceutical Forms												
	- Autacriments												
	Master File Locations												

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

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

Create and Send ICSRs		s Create and	Create and Send Acks		WEB Trader		ICSRs C		Create and Send Product Reports				1	Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicate	Remove	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 Send Acks WEB Trader ICSRs							Crea	ate and Se	end Produc	ct Reports	Medicina	I Products	MedDRA		
	Reset Application	Reset Section	Clear	Validate	Send	XML	ZIP	RTF	Duplicat	te Remov	e E L	R			
⊡ · X	EVPRM Message									Luna 21*					
6	⊨ Products											Description	Name/Valu	3	
	Update (2) - Authority	rised (2) - PRD1	12205 - Lu	una 21 Ph	armaL cor	tracept	ive tab	lets			Product	Attachment	Luna 21 Sn	PC (EN)	
	Medicinal Proc	uct Types (1)									Validity	declaration	Valid (1)		
	Conditional	Marketing Autho	risation (A	rticle 14 (of Regu 	lation (l	EC) No	0 /26/20	004) (4)						
	- Authorised Ph	armaceutical For	ms (1)												
	Dharmacoution	Droducto (1)													
	Drug ATCs (1)														
	Drug Indication	s (2)								Message from webpage				x	
	Previous EV C	odes (-)									Micssage no	in webpage			
	Product Attack	ments (1)													
	Luna 21_Sr	nPC (EN)										Send Operatio	on Completed		- 18
	Substances											If Vou want to	View the File	(a) Sant Click (O	
	Sources											II YOU Want to	o view the File	s) sent click [O	
	Organisations														
	-ATC Codes										01				
	Pharmaceutical Forms										OK	Can	cel		
	Routes Of Administration														
	Attachments												_		
	Master File Location	3													

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.er	na.europa.eu/X/?XI=6 - Windows Internet Explorer
Summar	y
Temporary	Click <u>here</u> for the file
(for	
Export)	Name: dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Update_PRD112205-2014-09-05+13.52.35-01.xml
	EVPRM Zipped Message
	Message Number: Update_PRD112205
To the	Name:
Outbox	
	EVPRM Zipped Message
	Message Number: Update_PRD112205

1.5. Retrieve the XEVPRM Acknowledgement (XEVPRM ACK)

1) Go to the "Web Trader" section

Create and Send ICSRs		Create and	Send Acks	WEB Trade	er ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA
	Reset Application	Reset Section	Clear Lo	cal Import C	reate 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 and Send Acks	WEB Trader ICSRs	Create and Send Product Reports	Medicinal Products	MedDRA
□ Reset Application R	eset Section Clear Re	mote Import Create Ack	0		
Imported Messages (-)					
Outbox					
-Run to Excel Files					
Terretaria					

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 Send A	ks WEB Trader	ICSRs	Create and Send Product Repo	orts Medicin	al Products	MedDRA	
Reset Application Reset Section Clear	Remote Import C	reate Ack	0				-
Imported Messages (-)	Luna 21*						
Inbox	Num Name			Num/Count	Date		Size
	0001 ack dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Upd	0/16	2014/09/05	13:58.08	00000031
Archive	0002 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/09/01	15:33.28	0000050
- Archive	0003 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/27	14:18.43	0000030
	0004 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/27	11:02.41	00000037
	0005 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/22	12:35.56	00000050
	0006 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/07/30	13:43.28	00000031
	0007 ack_dcmte	stmahtt-Sen	d-DCMTESTMAH-XEVPRM-Inse	0/16	2014/07/30	11:20.27	00000031
	0008 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-QPP	0/16	2014/07/17	14:52.39	00000030
	0009 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02	15:03.57	00000037
	0010 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02	11:19.56	00000044
	0011 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Upd	0/16	2014/07/02	11:11.56	00000030
	0012 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02	10:07.55	00000044
	0013 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02	10:05.55	00000043
	0014 ack_alcinite	estman-Send	I-DCMTESTMAH-XEVPRM-Drug	0/16	2014/06/26	13:22.16	00000049
	0015 ack_alcinite	estman-Send	I-DOMIESIMAH-XEVPRM-Nikk	0/16	2014/06/26	13:07.15	00000049
	0016 ack_alcinite	estmah-Send	I-DCMTESTMAH-XEVPRM-Test	0/16	2014/06/26	12:09.14	00000038

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	Num/Count	Date	Size
0001	ack dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Upd	0/16	2014/09/05 13:58.08	00000031
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/09/01 15:33.28	0000050
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/27 14:18.43	00000030
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/27 11:02.41	00000037
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/08/22 12:35.56	00000050
0006	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/07/30 13:43.28	00000031
0007	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Inse	0/16	2014/07/30 11:20.27	00000031
8000	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-QPP	0/16	2014/07/17 14:52.39	00000030
0009	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02 15:03.57	00000037
0010	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02 11:19.56	00000044
0011	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Upd	0/16	2014/07/02 11:11.56	00000030
0012	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02 10:07.55	00000044
0013	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Inser	0/16	2014/07/02 10:05.55	00000043
0014	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Drug	0/16	2014/06/26 13:22.16	00000049
0015	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Nikk	0/16	2014/06/26 13:07.15	00000049
0016	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Test	0/16	2014/06/26 12:09.14	0000038

Num	Name	Num/Count	Date	Size
0001	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Update_PRD112205-2014-09-05+13.52.35-01.xml	0/16	2014/09/05 13:58.08	00000031
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert of DMP-2014-09-01+15.28.47-01.xml	0/16	2014/09/01 15:33.28	00000050
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml	0/16	2014/08/27 14:18.43	0000030
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/16	2014/08/27 11:02.41	0000037
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/16	2014/08/22 12:35.56	00000050
0006	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/16	2014/07/30 13:43.28	00000031
0007	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/16	2014/07/30 11:20.27	00000031
8000	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-QPPV update-2014-07-14+15.01.39-01.xml	0/16	2014/07/17 14:52.39	0000030
0009	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_ProductX_vb-2014-07-02+14.59.32-01.xml	0/16	2014/07/02 15:03.57	00000037
0010	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Goshi 25 Capsules_vb-2014-07-02+11.15.28-01.xml	0/16	2014/07/02 11:19.56	00000044
0011	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Update_ORG4187_vb-2014-07-02+11.07.11-01.xml	0/16	2014/07/02 11:11.56	0000030
0012	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Nikko tablets_vb-2014-07-02+10.03.28-01.xml	0/16	2014/07/02 10:07.55	00000044
0013	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_DrugVero_vb-2014-07-02+10.01.59-01.xml	0/16	2014/07/02 10:05.55	00000043
0014	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-DrugVero_insert_vb-2014-06-26+13.17.33-01.xml	0/16	2014/06/26 13:22.16	00000049
0015	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Nikko tablets_insert_vb-2014-06-26+13.01.53-01.xml	0/16	2014/06/26 13:07.15	00000049
0016	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Test product_insert_vb-2014-06-26+12.04.10-01.xml	0/16	2014/06/26 12:09.14	0000038

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

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

Num	Name	Num/Count	Date	Size
0001	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Update_PRD112205-2014-09-05+13.52.35-01.xml	0/16	2014/09/05 13:58.08	00000031
0002	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert of DMP-2014-09-01+15.28.47-01.xml	0/16	2014/09/01 15:33.28	00000050
0003	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MFL-2014-08-27+14.13.21-01.xml	0/16	2014/08/27 14:18.43	0000030
0004	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert MAH and sponsor-2014-08-27+10.58.16-01.xml	0/16	2014/08/27 11:02.41	0000037
0005	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Luna 21 PharmaL contraceptive tablets-2014-08-22+12.31.28-01.xml	0/16	2014/08/22 12:35.56	00000050
0006	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_Sponsor_AllenLab-2014-07-30+13.39.50-01.xml	0/16	2014/07/30 13:43.28	00000031
0007	ack_dcmtestmahtt-Send-DCMTESTMAH-XEVPRM-Insert_MAH_PharmaCompany Ltd-2014-07-30+11.16.29-01.xml	0/16	2014/07/30 11:20.27	00000031
8000	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-QPPV update-2014-07-14+15.01.39-01.xml	0/16	2014/07/17 14:52.39	0000030
0009	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_ProductX_vb-2014-07-02+14.59.32-01.xml	0/16	2014/07/02 15:03.57	0000037
0010	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Goshi 25 Capsules_vb-2014-07-02+11.15.28-01.xml	0/16	2014/07/02 11:19.56	00000044
0011	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Update_ORG4187_vb-2014-07-02+11.07.11-01.xml	0/16	2014/07/02 11:11.56	0000030
0012	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_Nikko tablets_vb-2014-07-02+10.03.28-01.xml	0/16	2014/07/02 10:07.55	00000044
0013	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Insert_DrugVero_vb-2014-07-02+10.01.59-01.xml	0/16	2014/07/02 10:05.55	00000043
0014	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-DrugVero_insert_vb-2014-06-26+13.17.33-01.xml	0/16	2014/06/26 13:22.16	00000049
0015	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Nikko tablets_insert_vb-2014-06-26+13.01.53-01.xml	0/16	2014/06/26 13:07.15	00000049
0016	ack_alcinitestmah-Send-DCMTESTMAH-XEVPRM-Test product_insert_vb-2014-06-26+12.04.10-01.xml	0/16	2014/06/26 12:09.14	0000038

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):



The update of your AMP was successful.

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

File	Edit View Favorites	Tools Help			
	New Tab Duplicate Tab New Window New Session Open Edit with Microsoft Wood	Ctrl+T Ctrl+K Ctrl+N Ctrl+O	JTF-16" ?> ww.w3.org/2001/XMLSchema-instance" on="http://eudravigilance.ema.europa.eu/schema/ackxevmpd.xsd"> messagetype> 		
	Save	Ctrl+S	28343-ACK		
	Close Tab	Ctrl+W	TEST //messagesendendenther> CMTESTMAH		
	Page Setup Print Print Preview	Ctrl+P	35529		
	Send Import and Export	•	-M-128343 date_PR0112205		
	Properties Work Offline Exit		entifier>EVTEST at>204 [40905135235		
	<transmissionacknowledgment> - <reportacknowledgment> AUTHORISEDPRODUCT <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> <localnumber></localnumber> </reportacknowledgment></transmissionacknowledgment>				

You have now successfully retrieved the XEVPRM Acknowledgement.