



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository

Changes introduced in v1.16.0.0



Product selection Procedure number: PSUSA/00000526/201806

Sequence number: *

MAH name	Product full name	Drug ingredient	Country...	Authorisation no.	EV Code	EMEA product/MR...
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder and solvent for...	CANAKINUMAB	NO	EU/1/09/564/003	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder and solvent for...	CANAKINUMAB	LI	EU/1/09/564/003	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder for solution for...	CANAKINUMAB	LI	EU/1/09/564/001	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg/ml solution for injection	CANAKINUMAB	IS	EU/1/09/564/004	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder for solution for...	CANAKINUMAB	EU	EU/1/09/564/002	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg/ml solution for injection	CANAKINUMAB	NO	EU/1/09/564/004	XXXXX	EMEA/H/C/001109
NOVARTIS EUROPHARM LIMITED	Ilaris 150 ma powder and solvent for...	CANAKINUMAB	EU	EU/1/09/564/003	XXXXX	EMEA/H/C/001109

In product selection screens for **PSUSA procedures** a new column has been added containing the EV Code for all products (CAPs and NAPs).

1. Select Procedure Number
2. Click Create Sequence button
3. In Product Selection screen a new column has been added displaying the product EV Code

Submission type: PSUR
 Subject to or related to a single assessment

Submission unit : initial

*Denotes mandatory fields

Non-EU single assessment

Member state : Greece
 Data lock point : DLP (dd/mm/yyyy)

Submission format: eCTD
 MAH products to which the submission relates: Product short name

ADAFERIN






BETAFACT

MAH name	Product full name	Country...	Authorisation No...	EV Code	EMA Product/MRP/DCP...
LFB BIOMEDICAMENTS	BETAFACT 50 NE/ml por és oldószér...	HU	OGYI-T-22056/03		FR/H/0156/001
LFB BIOMEDICAMENTS	BETAFACT 50 NE/ml por és oldószér...	HU	OGYI-T-22056/02	XXXXXX	FR/H/0156/001
LFB BIOMEDICAMENTS	BETAFACT 50 NE/ml por és oldószér...	HU	OGYI-T-22056/01	XXXXXX	FR/H/0156/001
VIANEX S.A.	BETAFACT 50 IU/mL, κόνις και διαλύτ...	GR	86513/16/06-11-2017	XXXXXX	FR/H/0156/001
VIANEX S.A.	BETAFACT 50 IU/mL, κόνις και διαλύτ...	GR	43725/14/06-11-2017	XXXXXX	FR/H/0156/001

- In product selection screens for **Non EU procedures** a new column has been added containing the EV Code.
1. Uncheck Subject to or related to a single assessment product
 2. Select Member State and the Data lock point
 3. Select the relevant products

Super admins are able to delete: Versions of Assessment **Report**





Results

PSUSA/0000089/201509 aliskiren, aliskiren / amlodipine, aliskiren / hydrochlorothiazide	☐	Document Type	Submit...	C...	Date Received ▾	Products (MAH)	
	☑	Template of Assessment Report	psur_a...	N...	05/09/2018 12:...		
	☑	Comment	wallac...	N...	29/08/2018 16:...		
	☑	Comment	wallac...	N...	29/08/2018 15:...		
	☑	Updated Assessment Report	wallac...	N...	29/08/2018 15:...		 ☑
	☑	Response	-	-	14/02/2017 14:...	Riprazo (Novartis europharm limited (ar...	

In the pop up window that appears with the different available versions of Assessment Report , user will be able to select the version he wants to delete and select the “Delete” button in the action column of each row.

Download versions






Assessment reports for procedure : PSUSA/00000089/201509

	Document Type	Sub...	Date Received	
✓	Updated Assessment Report	walla...	29/08/2018 15:48:51	
✓	Preliminary Assessment Re...	walla...	29/08/2018 15:47:54	
✓	Updated Assessment Report	user1	08/06/2018 15:05:02	
✓	Preliminary Assessment Re...	user1	08/06/2018 15:02:46	



Now super admins will be able to delete: Versions of Assessment Report **Templates**



Results

PSUSA/00000089/201509 aliskiren, aliskiren / amlodipine, aliskiren / hydrochlorothiazide	☰	Document Type	Submit...	C...	Date Received ▾	Products (MAH)	
	✓	Template of Assessment Report	psur_a...	N...	05/09/2018 12:...		
	✓	Comment	wallac...	N...	29/08/2018 16:...		
	✓	Comment	wallac...	N...	29/08/2018 15:...		
	✓	Updated Assessment Report	wallac...	N...	29/08/2018 15:...		
	✓	Response	-	-	14/02/2017 14:...	Riprazo (Novartis europarm limited (ar...	



In the pop up window that appears with the different available versions of Assessment Report Template , user will be able to select the version he wants to delete and select the "Delete" button in the action column of each row

Assessment report templates for procedure : PSUSA/00000089/201509

	Document Type	Submitter	Date Received	
✓	Template of Assessment...	psur_admin	05/09/2018 12:21:54	
✓	Template of Assessment...	psur_admin	29/08/2018 15:44:56	



Thank you for your attention

Further information

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