XEVMPD field Mapping - External Authorised Product

Authorised Product PRI

*For marketed medicinal products only.

*One Authorised Product PRI is created for each combination of Registration and Language present on the Medicinal Prouct Registration records related to the Medicinal Product.

*For products registered at the pack level, one PRI is created for each combination of Registration, Language and Packaging.

Related Records (Records joined to the PRI)	Field	Field Type	Vault Source Description	Мар	Source Object	Source Field	Note
	Name	Name	NA	PRI> Name field	product_report_itemv	namev	
	Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field	medicinal_productrim	namev	
	Product Data Submission	Į.		PRI> Product Report> Product Data Submission> Name field	product_data_submissionv	namev	
	Product Report			PRI> Product Report> Name field	product_reportv	namev	
	Product Report Item Type	Object Type	Object Type of PRI	PRI> Product Report Item Type field> Name field	product_report_itemv	object_typev	
	Registration	Reference Object	The registration for this PRI, per the registration and language on the medicinal product registration.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registration> Registraiton> Name field	registrationrim	name_v	
	МАН	Data Source	The registration holder on the registration reference above.	Registration> Registration Holder field	registrationrim	registration_holderrim	
	MAH Code	Term Code	The EV code on the organization which is the registration holder for the registration above.	Registration> Registration Holder field> Organization> EV Code field	organizationrim	ev_codev	
	MAH Code Text	Text	The text override for the MAH code field.	Registration> Registration Holder field> Organization> EV Code field	organizationrim	ev_codev	
	MFL	Data Source	Master file location referenced on the medicinal product record.	Medicinal Product> Master File Location field	medicinal_productrim	master_file_locationv	
	MFL Code	Term Code	EV code on the organization which is the MFL for the medicinal product referenced above.	Medicinal Product> Master File Location field> Organization> EV Code field.	organizationrim	ev_codev	
	MFL Code Text	Text	The text override for the MFL code field.	Medicinal Product> Master File Location field> Organization> EV Code field	organizationrim	ev_codev	
	QPPV	Data Source	The QPPV referenced on the medicinal product.	Medicinal Product> Qualified Person for Pharmacovigilance field	medicinal_productrim	qualified_person_for_pharmaco viglancev	
	QPPV Code	Term Code	The QPPV Code for the QPPV referenced on the medicinal product above.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> QPPV Code field	contactrim	qppv_codev	
	QPPV Code Text	Text	The text override for the QPPV code field.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> QPPV Code field	contactrim	qppv_codev	
	Enquiry Email	Data Source	The email for the QPPV referenced on the medicinal product.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> Email Address field.	contactrim	email_addressrim	
	Enquiry Email Text	Text	The text override for the enquiry email field.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> Email Address field.	contactrim	email_addressrim	
	Enquiry Phone	Data Source	The phone number for the QPPV referenced on the medicinal product.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> Telephone Number	contactrim	telephone_numberrim	

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Enquiry Phone Text	Text	The text override for the enquiry phone field.	Medicinal Product> Qualified Person for Pharmacovigilance field> Contact> Telephone Number	contact rim	telephone number rim	
Medical Device Type	Data Source	From the Medical Device Type on the Medicinal Product.	Medicinal Product> Medical Device Type field	medicinal_productrim	medical_device_typev	
Medical Device Code	Term Code	From the Medical Device Type on the Medicinal Product.	Medicinal Product> Medical Device Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	
Medical Device Code Text	Term Code Text	The text override for the medical device code field.	Medicinal Product> Medical Device Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	
Date Suspension Lifted	Data Source	From the Registration record.	Registration> Date Suspension Lifted field.	registrationrim	date_suspension_liftedv	
Date Suspension Lifted Text	Text	The text override for the data suspension lifted field.	Registration> Date Suspension Lifted field.	registrationrim	date_suspension_liftedv	
Sender Local Code	Data Source	From the Medicinal Product.	Medicinal Product> Lender Local Number field	medicinal_productrim	sender_local_codev	
Sender Local Code Text	Text	The text override for the sender local code fied.	Medicinal Product> Lender Local Number field	medicinal_productrim	sender_local_codev	
EV Code	Data Source	From the Medicinal Product Registration.	Medicinal Product Registration> EV Code	medicinal_product_registration_ _rim	ev_codev	
EV Code Text	Text	The text override for the EV code	Medicinal Product Registration > EV Code	medicinal_product_registration_ _rim	ev_codev	
Previous EV Codes	Data Source	From the Medicinaln Product Registration	Medicinal Product Registration> Previous EV Code	medicinal_product_registration_ _rim	previous_ev_codesv	
Previous EV Codes Text	Text	The text override for the Previous EV Codes field.	Medicinal Product Registration> Previous EV Code	medicinal_product_registration_ _rim	previous_ev_codesv	
Operation Type	Data Source	From the PDS.	Product Data Submission> Operation Type field.	product_data_submissionv	operation_typev	
Local Number	Data Source	The Vault ID of the Medicinal Product Regsitration record. Only used when the EV code is blank. (only used when Operation Type = Insert)	Medicinal Product Registration> ID	medicinal_product_registrationv	id	
Local Number Text	Text	The text override for the local number field.	Medicinal Product Registration> ID	medicinal_product_registration_ _v	id	
Medicinal Product Registration	Reference Object	Medicinal Product Regstration mapped based on combination of Medicnal Product and language.)	Medicinal Product> Medicinal Product Registration	medicinal_product_registration_	namev	
Comments	Data Source	From the Classification System related to the medicinal product. For Classification Object Types = Paediactric Indication, Reason for Nullification.	Medicinal Product> Classification System> Classification Value field.	classification system rim	classification value _ rim	Applicable ONLY when Operation Type = Nullification
Comments Text	Text	The text override for the comments field.	Medicinal Product> Classification System> Classification Value field.	classification system rim	classification value rim	
Name	Reference Object	NA	PRI> Name field	namev	No	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product	namev	No	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission	namev	No	
Product Report	Reference Object	Parent of PRI	PRI> Product Report	namev	No	
Product Report Item Type	Reference Object	Object Type of PRI	PRI> PRI Type	object_typev	No	

XEVMPD field Mapping - External Authorised Product

	Authorised Dosage Form	Data Source	Combined Dosage Form - If the product is complex, but	Medicinal Product> XEVMPD Combined Dosage Form field OR Medicinal Product> MP- Registration> Registration> Product> Manufactured Dosage Form field.	Yes	
Authorised Dosage Form	Authorised Dosage Form Code	Term Code	The EV code of the dosage form referenced above.	Medicinal Product> Combined Dosage Form field> CV> EV Code OR Medicinal Product> MP- Registration> Registered Product> Product> Manufactured Dosage Form field> CV> EV Code	Yes	
	Authorised Dosage Form Code Text	Text	The text override for the authorised dosage form code field.	Medicinal Product> Combined Dosage Form field> CV> EV Code OR Medicinal Product> MP- Registration> Registered Product> Product> Manufactured Dosage Form field> CV> EV Code		

XEVMPD field Mapping - External Authorisation

Authorisation PRI

*For marketed medicinal products only.

*One Authorisation PRI is created for each registration related to the Medicinal Product.

Field	Field Type	Vault Source Description	Мар	Source Object	Source Field	Note
Name	Name	The name of the registration related to the medicinal product.	PRI> Name field	product_report_itemv	namev	
Product Report Item Type	Object Type	The Object Type.	PRI> Object Type	product_report_itemv	object_typev	
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field	product_report_itemv	product_reportv	
Registration	Reference Object	The registration for this PRI, per the registration and language on the medicinal product registration.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registration> Registration> Name field	registrationrim	namev	
Medicinal Product Registration	Reference Object	Medicinal Product Regstration mapped based on combination of Medicnal Product and language.)	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registraion> Name field	medicinal_product_registrationv	namev	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field	medicinal_productrim	namev	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field	product_data_submissionv	namev	
Application	Reference Object	The application referenced by the registration	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product> Medicinal Product Registration> Registration> Application> Application Number field	applicationv	namev	
Authorisation Procedure	Data Source	This is the Procedure Type on the Application record related to the registration record.	Application> Procedure Type field	applicationv	application_procedurerim	
Authorisation Procedure Code	Term Code	This is the EV code of the Procedure Type on the Application record related to the registration record.	Application> Procedure Type field> CV> EV code field	controlled_vocabularyrim	ev_codev	
Authorisation Procedure Code Text	Text	The text override for the authorisation procedure code field.	Application> Procedure Type field> CV> EV code field	controlled_vocabularyrim	ev_codev	
MRP / DCP / EMEA Number	Data Source	The Procedure Number on the Application record related to the Registration.	SPECIAL HANDLING: Source field from Registration> IDMP Procedure Number field. If IDMP Procedure Number field is not populated, source field from Application> Application Number field.	registrationrim OR applicationv	idmp_procedure_numberv OR namev	
MRP / DCP / EMEA Number Text	Text	The text override for the MRP / DCP / EMEA Number field.	SPECIAL HANDLING: Source field from Registration> IDMP Procedure Number field. If IDMP Procedure Number field is not populated, source field from Application> Application Number field.	registrationrim	idmp_procedure_numberv OR namev	
Authorisation Country	Data Source	The Country references on the registration.	Registration> Country field	registrationrim	countryrim	If it is a centralised procedure application, value is set to EU.
Authorisation Country Code	Term Code	The country code of the country referenced by the registration.	Registration> Country> Country Code field	country_v	ev_codev	If it is a centralised procedure application, value is set to EU.
Authorisation Country Code Text	Text	The text override for the authorisation coutnry code field.	Registration> Country> Country Code field	country_v	ev_codev	
Authorisation Date	Data Source	This the Registration Start Date or Renewal Date on the Registration record. Renewal Date takes precedence if populated.	Registration> Registration Start Date field	registrationrim	registration_start_daterim	
Authorisation Date Text	Text	The text override for the authorisation date field.	Registration> Registration Start Date field	registrationrim	registration_start_daterim	
Authorisation Number	Data Source	This is the Registration Number from the Registration record.	Registration> Registration Number field	registrationrim	registration_numberrim	

XEVMPD field Mapping - External Authorisation

Authorisation Number Text	Text	The text override for the authorisation number field.	Registration> Registration Number field	registrationrim	registration_numberrim	
Authorisation Status	Data Source	This is the XEVMPD Authorisation Status field on the Registration record.	Registration> XEVMPD Authorisation Status field	registrationrim	xevmpd_authorisation_statusv	
Authorisation Status Code	Term Code	This is the EV Code for the XEVMPD Authorisation Status field on the Registration record.	Registration> XEVMPD Authorisation Status field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Authorisation Status Code Text	Text	The text override for the authorisation status code field.	Registration> XEVMPD Authorisation Status field> CV> EV Code	controlled_vocabularyrim	ev_codev	
EU Number	Data Source	The Registration number from the Registration record. This is the same a the Authorsation Number.	Registration> Registration Number field	registrationrim	registration_numberrim	Only populated when Procedure = Centralised
EU Number Text	Text	The text override for the EU number field.	Registration> Registration Number field	registrationrim	registration_numberrim	
Additional Monitoring	Data Source	The Additional Monitoring field on the Medicinal Product record.	Registration> Additional Monitoring field.	medicinal_productrim	additional_monitoring_mprim	
Additional Monitoring Code	Term Code	The Additional Monitoring Code on the Medicinal Product.	Registration> Additional Monitoring field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Additional Monitoring Code Text	Text	The text override for the additional monitoring code field.	Registration> Additional Monitoring field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Classification System	Reference Object	The Classification System record related to the Medicinal Product that are of object type Legal Basis for Authorisation.	Medicinal Product> Classification System> Name field	classification_systemrim	classification_systemrim	
Legal Basis	Data Source	The Legal Basis for Authorisation field on the Classification System object type related to the Medicinal Product.	Classification System> Legal Basis field	classification_systemrim	legal_basisv	
Legal Basis Code	Term Code	The Legal Basis for Authorisation Code field on the Classification System object type related to the Medicinal Product.	Classification System> Legal Basis field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Legal Basis Code Text	Text	The text override for the legal basis code field.	Classification System> Legal Basis field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Orphan Drug Status	Data Source	The Orphan Designation on the Medicinal Product record.	Medicinal Product> Orphan Designation field	medicinal_productrim	orphan_designationrim	
Orphan Drug Status Code	Term Code	The Orphan Designation Code on the Medicinal Poduct record.	Medicinal Product> Orphan Designation field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Orphan Drug Status Code Text	Text	The t ext override for the orphan drug status code field.	Medicinal Product> Orphan Designation field> CV> EV Code	controlled_vocabularyrim	ev_codev	
Withdrawn Date	Data Source	The Registration End Date on the Registration record.	Registration> Registration End Date field.	registrationrim	registration_end_daterim	
Withdrawn Date Text	Text	The text override for the withdrawn date field.	Registration> Registration End Date field.	registrationrim	registration_end_daterim	

XEVMPD field Mapping - External Development Product

Development Product PRI

*For investigational medicinal products only.

*One Development Product PRI is created for each combination of Registration and Language present on the Medicinal Product Registration records related to the Medicinal Product of type Investigational.

*For products registered at the pack level, one PRI is created for each combination of Registration, Language and Packaging.

Field	Field Type	Help Text	Мар	Source Object	Source Field	Note
Name	Name	NA	PRI> Name field	product_report_itemv	namev	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field	medicinal_productrim	namev	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field	product_data_submissionv	namev	
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field	product_reportv	namev	
Product Report Item Type	Object Type	Object Type of PRI	PRI> Product Report Item Type field> Name field	product_report_itemv	object_typev	
Registration	Reference Object	The registration for this PRI, per the registration and language on the medicinal product registration.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registration> Registration> Name field	registrationrim	namev	
МАН	Term Code	The EV code on the organization which is the registration holder for the registration above.	Registration> Registration Holder field> Organization> EV Code field	organizationrim	ev_codev	
MAH Code	Text	The text override for the MAH code field.	Registration> Registration Holder field> Organization> EV Code field	organizationrim	ev_codev	
MAH Code Text	Data Source	Master file location referenced on the medicinal product record.	Medicinal Product> Master File Location field	medicinal_productrim	master_file_locationv	
Medical Device Type	Data Source	From the Medical Device Type on the Medicinal Product.	Medicinal Product> Medical Device Type field	medicinal_productrim	medical_device_typev	
Medical Device Code	Term Code	From the Medical Device Type on the Medicinal Product.	Medicinal Product> Medical Device Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	
Medical Device Code Text	Term Code Text	The text override for the medical device code field.	Medicinal Product> Medical Device Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	
Sender Local Code	Data Source	From the Medicinal Product.	Medicinal Product> Lender Local Number field	medicinal_productrim	sender_local_codev	
Sender Local Code Text	Text	The text override for the sender local code fied.	Medicinal Product> Lender Local Number field	medicinal_productrim	sender_local_codev	
EV Code	Data Source	From the Medicinal Product Registration.	Medicinal Product Registration> EV Code	medicinal_productrim	ev_codev	
EV Code Text	Text	The text override for the EV code fi	Medicinal Product Registration> EV Code	medicinal_productrim	ev_codev	
Operation Type	Data Source	From the PDS.	Product Data Submission> Operation Type field.	product_data_submissionv	operation_typev	
Local Number	Data Source	The Vault ID of the Medicinal Product Regsitration record. Only used when the EV code is blank. (only used when Operation Type = Insert)	Medicinal Product Registration>	medicinal_product_registrationv	id	
Local Number Text	Text	The text override for the local number field.	Medicinal Product Registration> ID	medicinal_product_registrationv	id	
Medicinal Product Registration	Reference Object	Medicinal Product Regstration mapped based on combination of Medicnal Product and language.)	Medicinal Product> Medicinal Product Registration	medicinal_product_registrationv	namev	

XEVMPD field Mapping - External Development Product

Comments	Data Source			classification_systemrim	classification_valuerim	Applicable ONLY when Operation Type = Nullification
Comments Text	Text	onments field	Medicinal Product> Classification System> Classification Value field.	classification_systemrim	classification_valuerim	

XEVMPD field Mapping - External Presentation Name

Presentation Name PRI

*One Presentation Name Element PRI will be created for each Medicinal Product Full Name record of type development related to the Medicinal Product Registration related to the Medicinal Product.

*The Registration, Country and Language must be present for the record to be created.

Field	Field Type	Help Text	Мар	Source Object	Source Field	Notes
Name	Name	The name of the Presentation Name Part associated to the medicinal product.	PRI> Name field.	product_report_itemv	namev	
Product Report Item Type	Object Type	The Object Type.	PRI> Product Report Item Type field. product_report_itemv		object_typev	
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	
Registration	Reference Object	The registration for this PRI, per the registration and language on the medicinal product registration.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registration> Registration	registrationrim	namev	
Medicinal Product Registration	Reference Object	Medicinal Product Regstration mapped based on combination of Medicnal Product and language.)	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Registration	medicinal_product_registratio	namev	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product	medicinal_productrim	namev	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission	product_data_submissionv	namev	
Medicinal Product Full Name	Reference Object	The Medicinal Product Full Name associated with the Medicinal Product.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product Full Name	medicinal_product_full_name	medicinal_product_full_nam ev	
Medicinal Product Full Name	Source	The name assigned to the medicinal product.	Medicinal Product Full Name> Medicinal Product Full Name field.	medicinal_product_full_name v	medicinal_product_full_nam ev	
Medicinal Product Full Name Text	Text	NA	Medicinal Product Full Name> Medicinal Product Full Name field.	medicinal_product_full_name	medicinal_product_full_nam ev	
EV Code	Source	The EV code assigned to the devlopment product.	Medicinal Product> MP Registration> EV Code	medicinal_product_registrationv	ev_codev	
EV Code Text	Text	The text override for the EV code field.	Medicinal Product> MP Registration> EV Code	medicinal_product_registratio nv	ev_codev	
Package Description	Data Source	The Package Description field from the Medicinal Product Registration.	Medicinal Product Registration> Package Description field.	medicinal_product_registratio nv	package_descriptionv	
Package Description Text	Text	The text override for the package description field.	Medicinal Product Registration> Package Description field.	medicinal_product_registratio nv	package_descriptionv	
Medicinal Product Name Part	Reference Object	The Medicinal Product Name Part record that is a child of the Medicinal Product Full Name, which is a child of the Medicinal Product.	Medicinal Product Full Name> Medicinal Product Name Part> Name field.	medicinal_product_name_pa rtrim	namev	
Medicinal Product Company Name	Data Source	The Trademark or Company Name Part from the Medicinal Prouct Name Parts record(s).	Medicinal Product Name Part> Name Part Text	medicinal_product_name_pa rtrim	name_part_textv	

XEVMPD field Mapping - External Presentation Name

Medicinal Product Form Name	Data Source	The Pharmaceutical Dosage Form from th Medicinal Prouct Name Parts record (s).	Medicinal Product Name Part> Name Part Text	medicinal_product_name_pa rtrim	name_part_textv
Medicinal Product INN / Common Name	Data Source	The Scientific Name from the Medicinal Prouct Name Parts record(s).	Medicinal Product Name Part> Name Part Text	medicinal_product_name_partrim	name_part_textv
Medicinal Product Strength Name	Data Source	The Strength from the Medicinal Prouct Name Parts record(s).	Medicinal Product Name Part> Name Part Text	medicinal_product_name_partrim	name_part_textv
Medicinal Product Short Name	Data Source	The Invented Name from the Medicinal Prouct Name Parts record(s).	Medicinal Product Name Part> Name Part Text	medicinal_product_name_partrim	name_part_textv
Medicinal Product Name Text	Data Source	The text field with the corresponding name part from one of the 5 part types above.	Medicinal Product Name Part> Name Part Text	medicinal_product_name_pa rtrim	name_part_textv

XEVMPD field Mapping - External DEV Presentation Name

Development Presentation Name PRI

*One Presentation Name Element PRI will be created for each Medicinal Product Full Name record of type development related to the Medicinal Product Registration related to the Medicinal Product.

*The Registration, Country and Language must be present for the record to be created.

Field	Field Type	Help T ext	Мар	Source Object	Source Field	Display in Bulk Update	Note
		The name of the Presentation Name Part associated to the medicinal					
Name	Name	product.	PRI> Name field.	product_report_itemv	namev	No	
Product Report Item Type	Object Type	The Object Type.	PRI> Product Report Item Type field.	product_report_itemv	object_typev	No	
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	No	
Registration	Reference Object	The registration for this PRI, per the registration and language on the medicinal product registration.	PRI> Product Report> Product Data Submission > Medicinal Product> Medicinal Product Registration> Registration	registrationrim	namev	No	
Medicinal Product Registration	Reference Object	Medicinal Product Regstration mapped based on combination of Medicnal Product and language.)	PRI> Product Report> Product Data Submission > Medicinal Product> Medicinal Product Registration	medicinal_product_registrati	namev	No	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission > Medicinal Product	medicinal_productrim	namev	No	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission	product_data_submission v	namev	No	
Medicinal Product Full Name	Reference Object	The Medicinal Product Full Name associated with the Medicinal Product.	PRI> Product Report> Product Data Submission > Medicinal Product> Medicinal Product Full Name	medicinal_product_full_nam	medicinal_product_full_nam	No	
Medicinal Product Full Name	Source	The name assigned to the medicinal product.	Medicinal Product Full Name> Medicinal Product Full Name field.	medicinal_product_full_nam ev	medicinal_product_full_nam ev	No	
Medicinal Product Full Name Text	Text	NA	Medicinal Product Full Name> Medicinal Product Full Name field.	medicinal_product_full_nam ev	medicinal_product_full_nam ev	No	
EV Code	Source	The EV code assigned to the devlopment product.	Medicinal Product> MP Registration> EV Code	medicinal_product_registrationv	ev_codev	No	
EV Code Text	Text	The text override for the EV code field.	Medicinal Product> MP Registration> EV Code	medicinal_product_registrationv	ev_codev	No	
Other Name	Source	An alternate, descriptive name for the development product.	Medicinal Product Full Name> Alias	medicinal_product_full_nam ev	aliasv	No	
Other Name Text	Text	The text override for the other name field.	Medicinal Product Full Name> Alias	medicinal_product_full_nam ev	aliasv	No	
Product Code	Source	The code of the medicinal product, as referenced in the IB, if a product name is available, the product code is optional.	Medicinal Product Full Name> Product Code	medicinal_product_full_nam	product_codev	No	
Product Code Text	Text	The text override for the product code field.	Medicinal Product Full Name> Product Code	medicinal_product_full_nam ev	product_codev	No	

Pharmaceutical Product PRI

- *Created for both marketed and investigational medicinal products.
- *One Pharmaceutical Product PRI will be created for each Administered Product related to the Medicinal Product.
- *One Ingredient PRI will be created for each Active Substance or Inactive Ingredient related to the Administered Product related to the Medicinal Product.
- *One Administration Route PRI will be created for each Route of Administration record related to the Administered Product related to the Medicinal Product.

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Мар	Source Object	Source Field	Note
(Necords Joined to the FRI)	Name	Name	Help I ext	PRI> Name field.	product_report_item	namev	Note
	Product Report	Reference Object		PRI> Product Report> Name field.	product report v	namev	
	Product Report Item Type	Reference Object		PRI> Product Report Type field	product_report_itemv	object_typev	
	Product Data Submission	Reference Object		PRI> Product Report > Product Data Submission> name field.	product_data_submissi onv	namev	
	Medicinal Product	Reference Object		PRI> Product Report > Product Data Submission> Name field.	medicinal_productri	namev	
Pharmaceutical (Dose) Form	Administered Product	Reference Object		PRI> Product Report> Product Data Submission> Medicinal Product> Administered Product> Name field.	administered_product_ _rim	namev	
	Administered Pharmaceutical Form	Reference Object		Administered Product> Administrable Dosage Form (or Reference) field.	administered_product_ _rim	administrable_dosage_form_ _rim OR administrable_dosage_form_I urim	
	Administered Pharmaceutical Form Code	Term Code		Administered Product> Administrable Dosage Form field> CV> EV Code	controlled_vocabulary_ _rim	ev_codev	
	Administered Pharmaceutical Form Code Text			Administered Product> Administrable Dosage Form field> CV> EV Code	controlled_vocabulary_ _rim	ev_codev	
	Name	Name		PRI> Name field.	product_report_itemv	namev	
	Product Report	Reference Object		PRI> Product Report> Name field	product_reportv	namev	

Product Report Item Type	Object Type	PRI> Product Report Type field	product_report_itemv	object_typev	
Product Data Submission	Reference Object	PRI> Product Report > Product Data Submission> Name field.	product_data_submissi onv	namev	
Medicinal Product	Reference Object	PRI> Product Report > Product Data Submission> Medicinal Product> Name field.	medicinal_productri	namev	
Administered Product	Reference Object	PRI> Product Report > Product Data Submission> Medicinal Product> Administered Product > Name field.	administered_product_ _rim	namev	
Administered Product Active Substance	Reference Object	Administered Product> Administered Product Active Substance> Name field.	admin_prod_active_su bstancerim	namev	
Active Substance	Reference Object	Administered Product Active Substance> Active Substance> Name field.	drug_substancev	namev	
Active Substance Code	Term Code	Active Substance> EV Code filed	drug_substancev	ev_codev	
Active Substance Code Text	Text	Active Substance> EV Code filed	drug_substancev	ev_codev	
Active Substance Concentration Type	Data Source	Administered Product Active Substance> Concentration Type field	admin_prod_active_su bstancerim	concentration_typev	
Concentration Type Code	Term Code	Administered Product Active Substance> Concentration Type field> CV> EV Code field.	controlled_vocabulary_ _rim	ev_codev	
Concentration Type Code Text	Text	Administered Product Active Substance> Concentration Type field> CV> EV Code field.	controlled_vocabulary_ _rim	ev_codev	
Substance Low Range Presentation Value	Data Source	Administered Product Active Substance> Presentation Strength Lower Range Value field.	admin_prod_active_su bstancerim	presentation_strength_lower_ range_valuerim	

Active Substance

Substance Low Range Presentation Unit	Data Source	Administered Product Active Substance> Presentation Strength Lower Range Unit field.	admin_prod_active_su bstancerim	presentation_strength_lower_ range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
Substance Low Range Concentration Value	Data Source	Administered Product Active Substance> Concentration Strength Lower Range Value field.	admin_prod_active_su bstancerim	concentration_strength_lower _range_valuerim	
Substance Low Range Concentration Unit	Data Source	Administered Product Active Substance> Concentration Strength Lower Range Unit field.	admin_prod_active_su bstancerim	concentration_strength_lower _range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
Substance High Range Concentration Value	Data Source	Administered Product Active Substance> Concentration Strength Upper Range Value field.	admin_prod_active_su bstancerim	concentration_strength_upper _range_valuerim	
Substance High Range Concentration Unit	Data Source	Administered Product Active Substance> Concentration Strength Upper Range Unit field.	admin_prod_active_su bstancerim	concentration_strength_upper _range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
Name	Name	PRI> Name field.	product_report_itemv	namev	
Product Report	Reference Object	PRI> Product Report> Name field	product_reportv	namev	
Product Report Item Type	Object Type	PRI> Product Report Type field	product_report_itemv	object_typev	
Product Data Submission	Reference Object	PRI> Product Report > Product Data Submission> Name field.	Product Data Submission	namev	
Medicinal Product	Reference Object	PRI> Product Report > Product Data Submission> Medicinal Product> Name field.	product_data_submissi onv	namev	
Administered Product	Reference Object	PRI> Product Report> Product Data Submission> Medicinal Product> Administered Product> Name field.	administered_product_ _rim	namev	

PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product Reference Administered Product Active Substance Object --> Administered **Product Active** Substance --> Name admin prod active su field. bstance__rim name__v Administered Product Reference Inactive Ingredient --Active Substance Object >Active Substance --> Name field. drug_substance__v name__v Active Substance--> Active SubstanceCode EV Code field. Term Code drug substance v ev code v Active Substance Active Substance --> Text EV Code field. Code Text drug_substance__v ev_code__v Administered Product Active Substance Active Substance --> Data Source Concentration Type Concentration Type admin prod active su field. bstance rim concentration type v Administered Product Active Substance --> Concentration Type Concentration Type Code field --> CV --> EV admin prod active su Term Code Code bstance_rim ev_code__v Administered Product Active Substance --> Concentration Type Text Concentration Type Code Text field --> CV --> EV admin prod active su Code bstance_rim ev_code__v Administered Product Substance Low Active Substance --> Range Presentation Data Source Presentation Strength Value Lower Range Value admin prod active su presentation strength lower field. bstance rim range value rim This field is further split Substance Low Administered Product into Numerator and Range Presentation Data Source Active Substance --> Denominator Unit Prefix Unit Presentation Strength admin prod active su presentation strength lower and Numerator and Lower Range Unit field. bstance__rim range_unit__rim Denominator Suffix. Administered Product Substance Low Inactive Ingredient --> Range Concentration Data Source Concentration Strength Value Lower Range Value admin_prod_active_su concentration_strength_lower field. bstance__rim _range_value__rim This field is further split Substance Low Administered Product into Numerator and Range Concentration Data Source Active Substance --> Denominator Unit Prefix Unit Concentration Strength | admin_prod_active_su concentration_strength_lower and Numerator and

Lower Range Unit field. bstance__rim

Denominator Suffix.

_range_unit__rim

Adjuvant (IPRI)

	Substance High Range Concentration Value	Data Source	Administered Product Active Substance> Concentration Strength Upper Range Value field.	admin_prod_active_su	concentration_strength_upper _range_valuerim	
	Substance High Range Concentration Unit	Data Source	Administered Product Active Substance> Concentration Strength Upper Range Unit field.	_	concentration_strength_upper _range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Name	Name	PRI> Name field.	product_report_itemv	namev	
	Product Report	Reference Object	PRI> Product Report> Name field	product_reportv	namev	
	Product Report Item Type	Object Type	PRI> Product Report Type field	product_report_itemv	object_typev	
	Product Data Submission	Reference Object	PRI> Product Report > Product Data Submission> Name field.	Product Data Submission	namev	
	Medicinal Product	Reference Object	PRI> Product Report > Product Data Submission> Medicinal Product> Name field.	product_data_submissi	namev	
	Administered Product	Reference Object	PRI> Product Report> Product Data Submission> Medicinal Product> Administered Product> Name field.	administered_product_	name_v	
	Administered Product Inactive Ingredient	Reference Object	PRI> Product Report> Product Data Submission> Medicinal Product> Administered Product> Administered Product Inactive Ingredient> Name field.	administered_product_i nactive_ingredientri m	namev	
	Inactive Ingredient	Reference Object	Administered Product Inactive Ingredient> Inactive Ingredient> Name field.	excipient v	name_v	
	Inactive Ingredient Code	Term Code	Inactive Ingredient> EV Code field.	excipient_v	ev_codev	
	Inactive Ingredient Code Text	Text	Inactive Ingredient> EV Code field.	excipient_v	ev_codev	
Excipient (IPRI)	Inactive Ingredient Concentration Type	Data Source	Administered Product Inactive Ingredient> Concentration Type field.	administered_product_i nactive_ingredientri m	concentration_typev	

I .		1	1	1		1
	Concentration Type Code	Term Code	Administered Product Inactive Ingredient> Concentration Type field> CV> EV Code	administered_product_i nactive_ingredientri m	ev_codev	
	Concentration Type Code Text	Text	Administered Product Inactive Ingredient> Concentration Type field> CV> EV Code	administered_product_i nactive_ingredientri m	ev_codev	
	Substance Low Range Presentation Value	Data Source	Administered Product Inactive Ingredient> Presentation Strength Lower Range Value field.	administered_product_i nactive_ingredientri m	presentation_strength_lower_ range_valuerim	
	Substance Low Range Presentation Unit	Data Source	Administered Product Inactive Ingredient> Presentation Strength Lower Range Unit field.	administered_product_i nactive_ingredientri m	presentation_strength_lower_ range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Substance Low Range Concentration Value	Data Source	Administered Product Inactive Ingredient> Concentration Strength Lower Range Value field.	administered_product_i nactive_ingredientri m	concentration_strength_lower _range_valuerim	
	Substance Low Range Concentration Unit	Data Source	Administered Product Inactive Ingredient> Concentration Strength Lower Range Unit field.	administered_product_i nactive_ingredientri m	concentration_strength_lower _range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Substance High Range Concentration Value	Data Source	Administered Product Inactive Ingredient> Concentration Strength Upper Range Value field.	administered_product_i nactive_ingredientri m	concentration_strength_upper _range_valuerim	
	Substance High Range Concentration Unit	Data Source	Administered Product Inactive Ingredient> Concentration Strength Upper Range Unit field.	administered_product_i nactive_ingredientri m	concentration_strength_upper _range_unitrim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Name	Name	PRI> Name field.	product_report_itemv	namev	
	Product Report	Reference Object	PRI> Product Report -	-product_reportv	namev	
	Product Report Item Type	Object Type	PRI> Product Report Type field	product_report_itemv	object_typev	
	Product Data Submission	Reference Object	PRI> Product Report > Product Data Submission> name field.	product_data_submissi onv	namev	

	Medicinal Product	Reference Object	PRI> Product Report > Product Data Submission> Name field.	medicinal_productri	namev	
Administration Route (PRI)	Administered Product	Reference Object	PRI> Product Report > Product Data Submission> Medicinal Product> Administered Product > Name field.	administered_product_ _rim	namev	
	Administered Route Code	Term Code	Administered Product Route of Administration > Route of Administration field> CV> EV Code	controlled_vocabulary_ _rim	ev_codev	
	Administered Route Code Text	Text	Administered Product Route of Administration > Route of Administration field> CV> EV Code	controlled_vocabulary_ _rim	ev_codev	
	Administered Product Route of Admin	Reference Object	Administered Product> Administered Product Route of Administration> Name field.	administered_product_ route_of_adminrim	namev	
	Administration Route	Data Source	Administered Product Route of Administration > Route of Admin field.	administered_product_ route_of_adminrim	route_of_administrationrim	

NOTES:

For complex products, Administered Products must be created for all components, including devices, if the object type is Administered as Manufactured. If all components are not also Administered Product records, the generation of the Pharmaceutical Product Element will fail. If the Administered Product object type is Mixed or Modified, there is no check to ensure all components are included.

If there are multiple Administered Product records for the same complex product component, the generation of the Pharmaceutical Product Element will fail.

If the Reference Product or Reference Product Variant fields are not populated on the Administered Product, the generation of the Pharmaceutical Product Element will fail.

XEVMPD field Mapping - External Therapeutic Indication

Therapeutic Indication PRI

^{*}One Therapeutic Indication PRI will be created for each Coded Indication record related to the Medicinal Product.

Field	Field Type	Help T ext	Мар	Source Object	Source Field	Note
Name	Name	The name of the MedDRA term related to the medicinal product.	PRI> Name field.	product_report_itemv	namev	
Product Report Item Type	Object Type	The Object Type.	PRI> Product Report Item Type field.		object_typev	
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field.	medicinal_productrim	namev	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field.	1. – – –	namev	
Medicinal Product Coded Indication	Reference Object	The record that links the coded indication to the medicinal product.	PRI> Product Report> Product Data Submission> Medicinal Product> Medicinal Product> Coded Indication> Name field.		name_v	
Coded Indication	Reference Object	The MedDRA term.	Medicinal Product Coded Indication> Coded Indication> Name field.	coded_indicationrim	namev	
MedDRA Level						Hardcoded as LLT
MedDRA Term Code	Term Code	The LLT on the Coded Indication record.	Coded Indication> Term Code field.	coded_indicationrim	term_coderim	
MedDRA Term Code Text	Text	The text override for the MedDRA term code field.	Coded Indication> Term Code field.	coded_indicationrim	term_coderim	
MedDRA Version	Data Source	The version on the coded indication record.	Coded Indication> Term Code Version field.	coded_indicationrim	term_code_versionrim	
MedDRA Version Text	Text	The text override for the MedDRA version field.	Coded Indication> Term Code Version field.	coded_indicationrim	term_code_versionrim	

^{*}Created for both authorised and investigational medicinal products.

XEVMPD field Mapping - External Classification

Classification PRI

*One Classification PRI will be created for each Classification record related to the Medicinal Product, where Classification Type = ATC Code, Nullification Reason or Paediatric Use.

Field	Field Type	Help T ext	Мар	Source Object	Source Field	Note
Name	Name	The name of the registration related to the medicinal product.	PRI> Name field.	product_report_itemv	namev	NA
Product Report Item Type	Object Type	Object Type of PRI	PRI> Product Report Item Type field.	product_report_itemv	object_typev	NA
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	NA
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field.	medicinal_productrim	namev	NA
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field.	product_data_submissionv	namev	NA
Classification System	Reference Object	The classification record to which the product report item is related.	PDS> MP> Classification System	classification_systemrim	namev	NA
ATC Code	Data Source	The ATC Code field on the Classification System record related to the medicinal product.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	
ATC Code Text	Text	The text override for the ATC Code field.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	
Nullification Reason	Data Source	The Nullification Reason field on the Classification System record related to the medicinal product.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	
Nullification Reason Text	Text	The text override for the nullification reason field.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	
Paediatric Use	Data Source	The Paediatric Use field on the Classification System record related to the medicinal product.	Classification System> Paediatric Use field.	classification_systemrim	paediatric_usev	Marketed Only
Paediatric Use Text	Text	The text override for th paediatric use field.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	Marketed Only
Medicinal Product Type	Data Source	The Medicinal Product Type field on the Classification System record related to the medicinal product.	Classification System> Medicinal Product Type field.	classification_systemrim	medicinal_product_typev	Marketed Only
Medicinal Product Type Code	Term Code	The Medicinal Product type field on the Classification System record related to the medicinal product.	Classification System> Medicinal Product Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	Marketed Only
Medicinal Product Type Code Text	Text	The text override for the Medicinal Product type field.	Classification System> Medicinal Product Type field> CV> EV Code field	controlled_vocabularyrim	ev_codev	Marketed Only

^{*}Created for both authorised and investigational medicinal products.

XEVMPD field Mapping - External DEV Classification

Development Classification PRI

*One Classification PRI will be created for each Classification record related to the Medicinal Product, where Classification Type = ATC Code, Nullification Reason or Paediatric Use.

Field	Field Type	Help T ext	Мар	Source Object	Source Field	Display in Bulk Update	Note
Name	Name	The name of the registration related to the medicinal product.	PRI> Name field.	product_report_itemv	namev	No	NA
Product Report Item Type	Object Type	Object Type of PRI	PRI> Product Report Item Type field.	product_report_itemv	object_typev	No	NA
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	No	NA
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field.	medicinal_productrim	namev	No	NA
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field.	product_data_submissionv	namev	No	NA
Classification System	Reference Object	The classification record to which the product report item is related.	PDS> MP> Classification System	classification_systemrim	namev	No	NA
ATC Code	Data Source	The ATC Code field on the Classification System record related to the medicinal product.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	No	Only one of these fields will be populated per record. - The ATC Code is the EV code for an ATC term. (3.l.a. 1)
ATC Code Text	Text	The text override for the ATC Code field.	Classification System> Classification Value field.	classification system rim	classification system rim	No	
Nullification Reason	Data Source	The Nullification Reason field on the Classification System record related to the medicinal product.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	Yes	
Nullification Reason Text	Text	The text override for the nullification reason field.	Classification System> Classification Value field.	classification_systemrim	classification_systemrim	No	

XEVMPD field Mapping - External Attachment

Attachment PRI

- *Created for both authorised and investigational medicinal products.
- *One Attachment PRI will be created for each document in the library that references the Medicinal Product.
- *All investigational medicinal products must include the SmPC and the Investigator's Brochure.

Field	Field Type Vault Source Descript		It Source Description Map		Source Field	Note
Name	Name	The name of the document in the library that is related to the medicinal product.	PRI> Name field.	product_report_itemv	namev	
Product Report Item Type	Object Type	The Object Type.	PRI> Product Report Item Type field.	product_report_itemv		
Product Report	Reference Object	Parent of PRI	PRI> Product Report> Name field.	product_reportv	namev	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI> Product Report> Product Data Submission> Medicinal Product> Name field.	medicinal_productrim	namev	
Product Data Submission	Reference Object	PDS of Product Report	PRI> Product Report> Product Data Submission> Name field.	product_data_submissionv	namev	
Attached Document Reference	Data Source	A link to the document in the library.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document	Document	
Attachment Type	Data Source	Always set to PPI.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	NA	NA	Always set to PPI.
Attachment Name	Data Source	The Document Name in the library.	PRI> Name field.	product_report_itemv	namev	
Attackment Name Tout	T4	The text override for the attachment	DDI - News fold	and the second second		
Attachment Name Text	Text	name field.	PRI> Name field. PRI> Product Report> Product Data	product_report_itemv	namev	
Attachment File Name	Data Source	The File Name in the library.	Submission> Medicinal Product> Document	Document> File Name field.	filenamev	
Attachment File Name Text	Text	The text override for the attachment file name field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> File Name field.	filenamev	
Attachment File Type	Data Source	The format of the document	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Classification field.	classificationv	
Attachment File Type Text	Text	The text override for the attachment file type code field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Classification field.	classificationv	
Attachment Code	Term Code	The document EV code on the EMA system, pulled fromt he EV code on the document.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> EV Code field.	ev_codev	Only populate when you don't intent to send a new version to the EMA.
Attachment Code Text	Text	The text override for the attachment code field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> EV Code field.	ev_codev	
Attachment Version	Data Source	The attachment version on the document in the library.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Attachment Version field.	attachment_version_for_submissionv	
		The text override for the attachment	PRI> Product Report> Product Data Submission> Medicinal Product>			
Attachment Version Text	Text	version field.	Document	Document> Attachment Version field.	attachment_version_for_submissionv	
Attachment Date	Data Source	The attachment date field on the document in the library.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Attachment Version Date field.	attachment_version_date_for_submission	
Attachment Date Text	Text	The text override for the attachment date field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Attachment Version Date field.	attachment_version_date_for_submission	
Language Code	Term Code	The language code based on the language field on the document in the librabry.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Language field> Country> Country Code field.	country_coderim	
Language Code Text	Text	The text override for the language code field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document> Language field> Country> Country Code field.	country_coderim	
Local Number	Data Source	The document number on the document in the library.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document	ID	
Local Number Text	Text	The text override for the local number field.	PRI> Product Report> Product Data Submission> Medicinal Product> Document	Document	ID	
Operation Type	Data Source	The operation type on the product data submission.	PRI> Product Report> Product Data Submission> Operation Type field.	product_data_submissionv	operation_typev	Always Insert for attachment only submissions.
Validity Declaration	Data Source	The validity declaration on the	PRI> Validity Declaration field.	product_report_itemv	validity_declarationv	Always set to 1 for attachment only submissions.