Authorised Product PRI

***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.**

***Authorised PRI included in marketed medicinal product submissions only.**

Related Records (Records joined to the PRI)	Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
	Name	Name	NA	PRI --> Name field	product_report_item__v	name__v	
	Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field	medicinal_product__rim	name__v	
	Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field	product_data_submission__v	name__v	
	Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field	product_report__v	name__v	
	Product Report Item Type	Object Type	Object Type of PRI	PRI --> Product Report Item Type field --> Name field	product_report_item__v	object_type__v	
	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	registration__rim	name__v	
	MAH	Data Source	The registration holder on the registration reference above.	Registration --> Registration Holder field	registration__rim	registration_holder__rim	
	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	organization__rim	ev_code__v	
	MAH Code Text	Text	The text override for the MAH code field.	Registration --> Registration Holder field --> Organization --> EV Code field	organization__rim	ev_code__v	
	MFL	Data Source	Master file location referenced on the medicinal product record.	Medicinal Product --> Master File Location field	medicinal_product__rim	master_file_location__v	
	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.	organization__rim	ev_code__v	
	MFL Code Text	Text	The text override for the MFL code field.	Medicinal Product --> Master File Location field --> Organization --> EV Code field	organization__rim	ev_code__v	
	QPPV	Data Source	The QPPV referenced on the medicinal product.	Medicinal Product --> Qualified Person for Pharmacovigilance field	medicinal_product__rim	qualified_person_for_pharmacoviglance__v	
	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	contact__rim	qppv_code__v	
	QPPV Code Text	Text	The text override for the QPPV code field.	Medicinal Product --> Qualified Person for Pharmacovigilance field --> Contact --> QPPV Code field	contact__rim	qppv_code__v	
	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.	contact__rim	email_address__rim	

Authorised Product PRI

***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.**

***Authorised PRI included in marketed medicinal product submissions only.**

Related Records (Records joined to the PRI)	Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
	Name	Name	NA	PRI --> Name field	product_report_item__v	name__v	
	Enquiry Email Text	Text	The text override for the enquiry email field.	Medicinal Product --> Qualified Person for Pharmacovigilance field --> Contact --> Email Address field.	contact__rim	email_address__rim	
	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	contact__rim	telephone_number__rim	
	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_product__rim	medical_device_type__v	
	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_vocabulary__rim	ev_code__v	
	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_vocabulary__rim	ev_code__v	
	Date Suspension LIfted	Data Source	From the Registration record.	Registration --> Date Suspension Lifted field.	registration__rim	date_suspension_lifted__v	
	Date Suspension LIfted Text	Text	The text override for the data suspension lifted field.	Registration --> Date Suspension Lifted field.	registration__rim	date_suspension_lifted__v	
	Sender Local Code	Data Source	From the Medicinal Product.	Medicinal Product --> Lender Local Number field	medicinal_product__rim	sender_local_code__v	
	Sender Local Code Text	Text	The text override for the sender local code fied.	Medicinal Product --> Lender Local Number field	medicinal_product__rim	sender_local_code__v	
	EV Code	Data Source	From the Medicinal Product Registration.	Medicinal Product --> EV Code	medicinal_product__rim	ev_code__v	
	EV Code Text	Text	The text override for the EV code	Medicinal Product --> EV Code	medicinal_product__rim	ev_code__v	
	Operation Type	Data Source	From the PDS.	Product Data Submission --> Operation Type field.	product_data_submission__v	operation_type__v	
	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_registration__v	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__v	name__v	
	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

Authorised Product PRI

***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.**

***Authorised PRI included in marketed medicinal product submissions only.**

Related Records (Records joined to the PRI)	Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
	Name	Name	NA	PRI --> Name field	product_report_item__v	name__v	
	Comments Text	Text	The text override for the comments field.	Medicinal Product --> Classification System --> Classification Value field.	classification_system__rim	classification_value__rim	
Authorised Dosage Form	Name	Reference Object	NA	PRI --> Name field	name__v	No	
	Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product	name__v	No	
	Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission	name__v	No	
	Product Report	Reference Object	Parent of PRI	PRI --> Product Report	name__v	No	
	Product Report Item Type	Reference Object	Object Type of PRI	PRI --> PRI Type	object_type__v	No	
	Authorised Dosage Form	Data Source	The Combined Dosage Form field on the Medicinal Product record, when populated. If the Combined Dosage Form is blank, the Dosage Form of the Drug Product referenced on the Registrations related to the Medicinal Product.	Medicinal Product --> Combined Dosage Form field OR Medicinal Product --> MP-Registration --> Registration --> Registered Product --> Product --> Manufactured Dosage Form field.	combined_dosage_form__rim OR manufactured_dosage_form__rim	Yes	
	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 --> Registration --> Registered Product --> Product --> Manufactured Dosage Form field --> CV --> EV Code	ev_code__v	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 --> Registration --> Registered Product --> Product --> Manufactured Dosage Form field --> CV --> EV Code	ev_code__v		

Authorisation PRI

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

***Authorisation PRI included in marketed medicinal product submissions only.**

Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
Name	Name	The name of the registration related to the medicinal product.	PRI --> Name field	product_report_item__v	name__v	
Product Report Item Type	Object Type	The Object Type.	PRI --> Object Type	product_report_item__v	object_type__v	
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field	product_report_item__v	product_report__v	
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 Registraion --> Registration --> Name field	registration__rim	name__v	
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_registration__v	name__v	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field	medicinal_product__rim	name__v	
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field	product_data_submission__v	name__v	
Application	Reference Object	The application referenced by the registration	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Medicinal Product Registraion --> Registration --> Application --> Application Number field	application__v	name__v	
Authorisation Procedure	Data Source	This is the Procedure Type on the Application record related to the registration record.	Application --> Procedure Type field	application__v	application_procedure__rim	
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_vocabulary__rim	ev_code__v	
Authorisation Procedure Code Text	Text	The text override for the authorisation procedure code field.	Application --> Procedure Type field --> CV --> EV code field	controlled_vocabulary__rim	ev_code__v	
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.	registration__rim OR application__v	idmp_procedure_number__v OR name__v	
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.	registration__rim OR application__v	idmp_procedure_number__v OR name__v	
Authorisation Country	Data Source	The Country references on the registration.	Registration --> Country field	registration__rim	country__rim	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_code__v	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_code__v	

Authorisation PRI

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

***Authorisation PRI included in marketed medicinal product submissions only.**

Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
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	registration__rim	registration_start_date__rim	
Authorisation Date Text	Text	The text override for the authorisation date field.	Registration --> Registration Start Date field	registration__rim	registration_start_date__rim	
Authorisation Number	Data Source	This is the Registration Number from the Registration record.	Registration --> Registration Number field	registration__rim	registration_number__rim	
Authorisation Number Text	Text	The text override for the authorisation number field.	Registration --> Registration Number field	registration__rim	registration_number__rim	
Authorisation Status	Data Source	This is the XEVMPD Authorisation Status field on the Registration record.	Registration --> XEVMPD Authorisation Status field	registration__rim	xevmpd_authorisation_status__v	
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_vocabulary__rim	ev_code__v	
Authorisation Status Code Text	Text	The text override for the authorisation status code field.	Registration --> XEVMPD Authorisation Status field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
EU Number	Data Source	The Regstration number from the Registration record. This is the same a the Authorsation Number.	Registration --> Registration Number field	registration__rim	registration_number__rim	Only populated when Procedure = Centralised
EU Number Text	Text	The text override for the EU number field.	Registration --> Registration Number field	registration__rim	registration_number__rim	
Additional Monitoring	Data Source	The Additional Monitoring field on the Medicinal Product record.	Registration --> Additional Monitoring field.	medicinal_product__rim	additional_monitoring_mp__rim	
Additional Monitoring Code	Term Code	The Additional Monitoring Code on the Medicinal Product.	Registration --> Additional Monitoring field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
Additional Monitoring Code Text	Text	The text override for the additional monitoring code field.	Registration --> Additional Monitoring field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
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_system__rim	classification_system__rim	
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_system__rim	legal_basis__v	
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_vocabulary__rim	ev_code__v	
Legal Basis Code Text	Text	The text override for the legal basis code field.	Classification System --> Legal Basis field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
Orphan Drug Status	Data Source	The Orphan Designation on the Medicinal Product record.	Medicinal Product --> Orphan Designation field	medicinal_product__rim	orphan_designation__rim	
Orphan Drug Status Code	Term Code	The Orphan Designation Code on the Medicinal Poduct record.	Medicinal Product --> Orphan Designation field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
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_vocabulary__rim	ev_code__v	
Withdrawn Date	Data Source	The Registration End Date on the Registration record.	Registration --> Registration End Date field.	registration__rim	registration_end_date__rim	
Withdrawn Date Text	Text	The text override for the withdrawn date field.	Registration --> Registration End Date field.	registration__rim	registration_end_date__rim	

Development Product PRI

***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.**

***Development PRI included in investigational medicinal product submissions only.**

Field	Field Type	Help Text	Map	Source Object	Source Field	Note
Name	Name	NA	PRI --> Name field	product_report_item__v	name__v	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field	medicinal_product__rim	name__v	
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field	product_data_submission__v	name__v	
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field	product_report__v	name__v	
Product Report Item Type	Object Type	Object Type of PRI	PRI --> Product Report Item Type field --> Name field	product_report_item__v	object_type__v	
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	registration__rim	name__v	
MAH	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	organization__rim	ev_code__v	
MAH Code	Text	The text override for the MAH code field.	Registration --> Registration Holder field --> Organization --> EV Code field	organization__rim	ev_code__v	
MAH Code Text	Data Source	Master file location referenced on the medicinal product record.	Medicinal Product --> Master File Location field	medicinal_product__rim	master_file_location__v	
Medical Device Type	Data Source	From the Medical Device Type on the Medicinal Product.	Medicinal Product --> Medical Device Type field	medicinal_product__rim	medical_device_type__v	
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_vocabulary__rim	ev_code__v	
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_vocabulary__rim	ev_code__v	
Sender Local Code	Data Source	From the Medicinal Product.	Medicinal Product --> Lender Local Number field	medicinal_product__rim	sender_local_code__v	
Sender Local Code Text	Text	The text override for the sender local code fied.	Medicinal Product --> Lender Local Number field	medicinal_product__rim	sender_local_code__v	
EV Code	Data Source	From the Medicinal Product Registration.	Medicinal Product --> EV Code	medicinal_product__rim	ev_code__v	
EV Code Text	Text	The text override for the EV code fi	Medicinal Product --> EV Code	medicinal_product__rim	ev_code__v	
Operation Type	Data Source	From the PDS.	Product Data Submission --> Operation Type field.	product_data_submission__v	operation_type__v	
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_registration__v	id	
Local Number Text	Text	The text override for the local number field.	Medicinal Product Registration --> ID	medicinal_product_registration__v	id	

Development Product PRI

***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.**

***Development PRI included in investigational medicinal product submissions only.**

Field	Field Type	Help Text	Map	Source Object	Source Field	Note
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__v	name__v	
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	

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.**

***For both authorised and investigational products.**

Field	Field Type	Help Text	Map	Source Object	Source Field	Notes
Name	Name	The name of the Presentation Name Part associated to the medicinal product.	PRI --> Name field.	product_report_item__v	name__v	
Product Report Item Type	Object Type	The Object Type.	PRI --> Product Report Item Type field.	product_report_item__v	object_type__v	
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field.	product_report__v	name__v	
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	registration__rim	name__v	
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_registration__v	name__v	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product	medicinal_product__rim	name__v	
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission	product_data_submission__v	name__v	
Medicinal Product Full Name	Reference Objec	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__v	medicinal_product_full_name__v	
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_name__v	
Medicinal Product Full Name Text	Text	NA	Medicinal Product Full Name --> Medicinal Product Full Name field.	medicinal_product_full_name__v	medicinal_product_full_name__v	
EV Code	Source	The EV code assigned to the devlopment product.	Medicinal Product --> MP Registration --> EV Code	medicinal_product_registration__v	ev_code__v	
EV Code Text	Text	The text override for the EV code field.	Medicinal Product --> MP Registration --> EV Code	medicinal_product_registration__v	ev_code__v	
Other Name	Source	An alternate, descriptive name for the development product.	Medicinal Product Full Name --> Alias	medicinal_product_full_name__v	alias__v	
Other Name Text	Text	The text override for the other name field.	Medicinal Product Full Name --> Alias	medicinal_product_full_name__v	alias__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
	Name	Name		PRI --> Name field.	product_report_item__v	name__v	
	Product Report	Reference Object		PRI --> Product Report --> Name field	product_report__v	name__v	
	Product Report Item Type	Object Type		PRI --> Product Report Type field	product_report_item__v	object_type__v	
	Product Data Submission	Reference Object		PRI --> Product Report --> Product Data Submission --> Name field.	product_data_submission__v	name__v	
	Medicinal Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	medicinal_product__rim	name__v	
	Administered Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product --> Name field.	administered_product__rim	name__v	
	Administered Product Active Substance	Reference Object		Administered Product --> Administered Product Active Substance --> Name field.	admin_prod_active_substance__rim	name__v	
	Active Substance	Reference Object		Administered Product Active Substance --> Active Substance --> Name field.	drug_substance__v	name__v	
	Active Substance Code	Term Code		Active Substance --> EV Code filed	drug_substance__v	ev_code__v	
	Active Substance Code Text	Text		Active Substance --> EV Code filed	drug_substance__v	ev_code__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Active Substance	Active Substance Concentration Type	Data Source		Administered Product Active Substance --> Concentration Type field	admin_prod_active_substance__rim	concentration_type__v	
	Concentration Type Code	Term Code		Administered Product Active Substance --> Concentration Type field --> CV --> EV Code field.	controlled_vocabulary__rim	ev_code__v	
	Concentration Type Code Text	Text		Administered Product Active Substance --> Concentration Type field --> CV --> EV Code field.	controlled_vocabulary__rim	ev_code__v	
	Substance Low Range Presentation Value	Data Source		Administered Product Active Substance --> Presentation Strength Lower Range Value field.	admin_prod_active_substance__rim	presentation_strength_lower_range_value__rim	
	Substance Low Range Presentation Unit	Data Source		Administered Product Active Substance --> Presentation Strength Lower Range Unit field.	admin_prod_active_substance__rim	presentation_strength_lower_range_unit__rim	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_substance__rim	concentration_strength_lower_range_value__rim	
	Substance Low Range Concentration Unit	Data Source		Administered Product Active Substance --> Concentration Strength Lower Range Unit field.	admin_prod_active_substance__rim	concentration_strength_lower_range_unit__rim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
	Substance High Range Concentration Value	Data Source		Administered Product Active Substance --> Concentration Strength Upper Range Value field.	admin_prod_active_substance__rim	concentration_strength_upper_range_value__rim	
	Substance High Range Concentration Unit	Data Source		Administered Product Active Substance --> Concentration Strength Upper Range Unit field.	admin_prod_active_substance__rim	concentration_strength_upper_range_unit__rim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Name	Name		PRI --> Name field.	product_report_item__v	name__v	
	Product Report	Reference Object		PRI --> Product Report --> Name field	product_report__v	name__v	
	Product Report Item Type	Object Type		PRI --> Product Report Type field	product_report_item__v	object_type__v	
	Product Data Submission	Reference Object		PRI --> Product Report --> Product Data Submission --> Name field.	Product Data Submission	name__v	
	Medicinal Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	product_data_submission__v	name__v	
	Administered Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product --> Name field.	administered_product__rim	name__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Adjuvant (IPRI)	Administered Product Active Substance	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product --> Administered Product Active Substance --> Name field.	admin_prod_active_substance__rim	name__v	
	Active Substance	Reference Object		Administered Product Inactive Ingredient -->Active Substance --> Name field.	drug_substance__v	name__v	
	Active SubstanceCode	Term Code		Active Substance--> EV Code field.	drug_substance__v	ev_code__v	
	Active Substance Code Text	Text		Active Substance --> EV Code field.	drug_substance__v	ev_code__v	
	Active Substance Concentration Type	Data Source		Administered Product Active Substance --> Concentration Type field.	admin_prod_active_substance__rim	concentration_type__v	
	Concentration Type Code	Term Code		Administered Product Active Substance --> Concentration Type field --> CV --> EV Code	admin_prod_active_substance__rim	ev_code__v	
	Concentration Type Code Text	Text		Administered Product Active Substance --> Concentration Type field --> CV --> EV Code	admin_prod_active_substance__rim	ev_code__v	
	Substance Low Range Presentation Value	Data Source		Administered Product Active Substance --> Presentation Strength Lower Range Value field.	admin_prod_active_substance__rim	presentation_strength_lower_range_value__rim	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
	Substance Low Range Presentation Unit	Data Source		Administered Product Active Substance --> Presentation Strength Lower Range Unit field.	admin_prod_active_substance__rim	presentation_strength_lower_range_unit__rim	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.	admin_prod_active_substance__rim	concentration_strength_lower_range_value__rim	
	Substance Low Range Concentration Unit	Data Source		Administered Product Active Substance --> Concentration Strength Lower Range Unit field.	admin_prod_active_substance__rim	concentration_strength_lower_range_unit__rim	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_substance__rim	concentration_strength_upper_range_value__rim	
	Substance High Range Concentration Unit	Data Source		Administered Product Active Substance --> Concentration Strength Upper Range Unit field.	admin_prod_active_substance__rim	concentration_strength_upper_range_unit__rim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Name	Name		PRI --> Name field.	product_report_item__v	name__v	
	Product Report	Reference Object		PRI --> Product Report --> Name field	product_report__v	name__v	
	Product Report Item Type	Object Type		PRI --> Product Report Type field	product_report_item__v	object_type__v	
	Product Data Submission	Reference Object		PRI --> Product Report --> Product Data Submission --> Name field.	Product Data Submission	name__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Excipient (IPRI)	Medicinal Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	product_data_submission__v	name__v	
	Administered Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product --> Name field.	administered_product__rim	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_inactive_ingredient__rim	name__v	
	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_code__v	
	Inactive Ingredient Code Text	Text		Inactive Ingredient --> EV Code field.	excipient__v	ev_code__v	
	Inactive Ingredient Concentration Type	Data Source		Administered Product Inactive Ingredient --> Concentration Type field.	administered_product_inactive_ingredient__rim	concentration_type__v	
	Concentration Type Code	Term Code		Administered Product Inactive Ingredient --> Concentration Type field --> CV --> EV Code	administered_product_inactive_ingredient__rim	ev_code__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
	Concentration Type Code Text	Text		Administered Product Inactive Ingredient --> Concentration Type field --> CV --> EV Code	administered_product_inactive_ingredient__rim	ev_code__v	
	Substance Low Range Presentation Value	Data Source		Administered Product Inactive Ingredient --> Presentation Strength Lower Range Value field.	administered_product_inactive_ingredient__rim	presentation_strength_lower_range_value__rim	
	Substance Low Range Presentation Unit	Data Source		Administered Product Inactive Ingredient --> Presentation Strength Lower Range Unit field.	administered_product_inactive_ingredient__rim	presentation_strength_lower_range_unit__rim	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_inactive_ingredient__rim	concentration_strength_lower_range_value__rim	
	Substance Low Range Concentration Unit	Data Source		Administered Product Inactive Ingredient --> Concentration Strength Lower Range Unit field.	administered_product_inactive_ingredient__rim	concentration_strength_lower_range_unit__rim	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_inactive_ingredient__rim	concentration_strength_upper_range_value__rim	
	Substance High Range Concentration Unit	Data Source		Administered Product Inactive Ingredient --> Concentration Strength Upper Range Unit field.	administered_product_inactive_ingredient__rim	concentration_strength_upper_range_unit__rim	This field is further split into Numerator and Denominator Unit Prefix and Numerator and Denominator Suffix.
	Name	Name		PRI --> Name field.	product_report_item__v	name__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Administration Route (PRI)	Product Report	Reference Object		PRI --> Product Report -	product_report__v	name__v	
	Product Report Item Type	Object Type		PRI --> Product Report Type field	product_report_item__v	object_type__v	
	Product Data Submission	Reference Object		PRI --> Product Report --> Product Data Submission --> name field.	product_data_submission__v	name__v	
	Medicinal Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Name field.	medicinal_product__rim	name__v	
	Administered Product	Reference Object		PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Administered Product --> Name field.	administered_product__rim	name__v	
	Administered Route Code	Term Code		Administered Product Route of Administration --> Route of Administration field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
	Administered Route Code Text	Text		Administered Product Route of Administration --> Route of Administration field --> CV --> EV Code	controlled_vocabulary__rim	ev_code__v	
	Administered Product Route of Admin	Reference Object		Administered Product --> Administered Product Route of Administration --> Name field.	administered_product_route_of_admin__rim	name__v	

Pharmaceutical Product PRI

***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.**

***For both authorised and investigational products.**

Related Records (Records joined to the PRI)	Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
	Administration Route	Data Source		Administered Product Route of Administration --> Route of Admin field.	administered_product_route_of_admin__rim	route_of_administration__rim	

Therapeutic Indication PRI

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

***For both authorised and investigational products.**

Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Name	Name	The name of the MedDRA term related to the medicinal product.	PRI --> Name field.	product_report_item__v	name__v	
Product Report Item Type	Object Type	The Object Type.	PRI --> Product Report Item Type field.	product_report_item__v	object_type__v	
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field.	product_report__v	name__v	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	medicinal_product__rim	name__v	
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field.	product_data_submission__v	name__v	
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.	medicinal_product_coded_indication__v	name__v	
Coded Indication	Reference Object	The MedDRA term.	Medicinal Product Coded Indication --> Coded Indication --> Name field.	coded_indication__rim	name__v	
MedDRA Term Code	Term Code	The LLT on the Coded Indication record.	Coded Indication --> Term Code field.	coded_indication__rim	term_code__rim	
MedDRA Term Code Text	Text	The text override for the MedDRA term code field.	Coded Indication --> Term Code field.	coded_indication__rim	term_code__rim	
MedDRA Term Name	Data Source	The full name on the coded indication record.	Coded Indication --> Name field	coded_indication__rim	name__v	
MedDRA Term Name Text	Text	The text override for the MedDRA term name field.	Coded Indication --> Name field	coded_indication__rim	name__v	
MedDRA Version	Data Source	The version on the coded indication record.	Coded Indication --> Term Code Version field.	coded_indication__rim	term_code_version__rim	
MedDRA Version Text	Text	The text override for the MedDRA version field.	Coded Indication --> Term Code Version field.	coded_indication__rim	term_code_version__rim	

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.**

***For both authorised and investigational products.**

Field	Field Type	Help T ext	Map	Source Object	Source Field	Note
Name	Name	The name of the registration related to the medicinal product.	PRI --> Name field.	product_report_item__v	name__v	NA
Product Report Item Type	Object Type	Object Type of PRI	PRI --> Product Report Item Type field.	product_report_item__v	object_type__v	NA
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field.	product_report__v	name__v	NA
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	medicinal_product__rim	name__v	NA
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field.	product_data_submission__v	name__v	NA
Classification System	Reference Object	The classification record to which the product report item is related.	PDS --> MP --> Classification System	classification_system__rim	name__v	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_system__rim	classification_system__rim	Only one of these fields will be populated per record. - The ATC Code is the EV code for an ATC term. (3.I.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	
Nullification Reason	Data Source	The Nullification Reason field on the Classification System record related to the medicinal product.	Classification System --> Classification Value field.	classification_system__rim	classification_system__rim	
Nullification Reason Text	Text	The text override for the nullification reason field.	Classification System --> Classification Value field.	classification_system__rim	classification_system__rim	

Attachment PRI

***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.**

***For both authorised and investigational products.**

Field	Field Type	Vault Source Description	Map	Source Object	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_item__v	name__v	
Product Report Item Type	Object Type	The Object Type.	PRI --> Product Report Item Type field.	product_report_item__v		
Product Report	Reference Object	Parent of PRI	PRI --> Product Report --> Name field.	product_report__v	name__v	
Medicinal Product	Reference Object	PDS Medicinal Product	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Name field.	medicinal_product__rim	name__v	
Product Data Submission	Reference Object	PDS of Product Report	PRI --> Product Report --> Product Data Submission --> Name field.	product_data_submission__v	name__v	
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_item__v	name__v	
Attachment Name Text	Text	The text override for the attachment name field.	PRI --> Name field.	product_report_item__v	name__v	
Attachment File Name	Data Source	The File Name in the library.	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Document	Document --> File Name field.	filename__v	
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.	filename__v	
Attachment File Type	Data Source	The format of the document	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Document	Document --> Classification field.	classification__v	
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.	classification__v	
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_code__v	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_code__v	
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_submission__v	
Attachment Version Text	Text	The text override for the attachment version field.	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Document	Document --> Attachment Version field.	attachment_version_for_submission__v	
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__v	
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__v	
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_code__rim	
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_code__rim	
Local Number	Data Source	The document number on the document in the library.	PRI --> Product Report --> Product Data Submission --> Medicinal Product --> Document	Document	ID	

Attachment PRI

***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.**

***For both authorised and investigational products.**

Field	Field Type	Vault Source Description	Map	Source Object	Source Field	Note
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_submission__v	operation_type__v	Always Insert for attachment only submissions.
Validity Declaration	Data Source	The validity declaration on the	PRI --> Validity Declaration field.	product_report_item__v	validity_declaration__v	Always set to 1 for attachment only submissions.