BAG Beispieldaten für IDMP

Datum	Emmenbrücke, 25. Januar 2024
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	Beispieldaten für IDMP
Thema	Dieses Dokument dient als Grundlage für den IDMP Datenaustausch in der Schweiz. Basierend auf diesen Beispielen wird die FHIR Spezifikation für das IDMP Projekt ePL erstellt. Diese Dokument Version dient dem Review der Beispieldaten.

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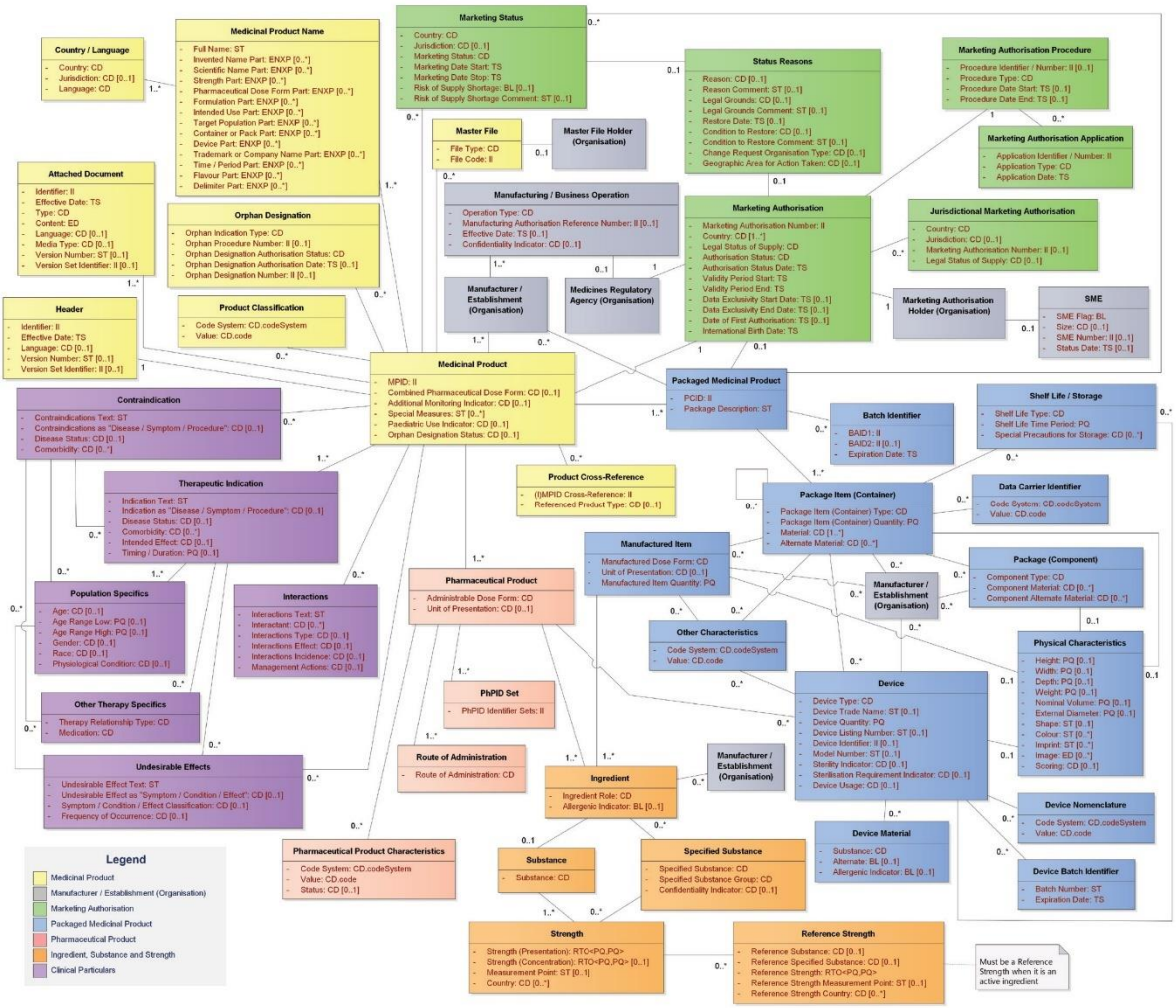
1 Datenmodel

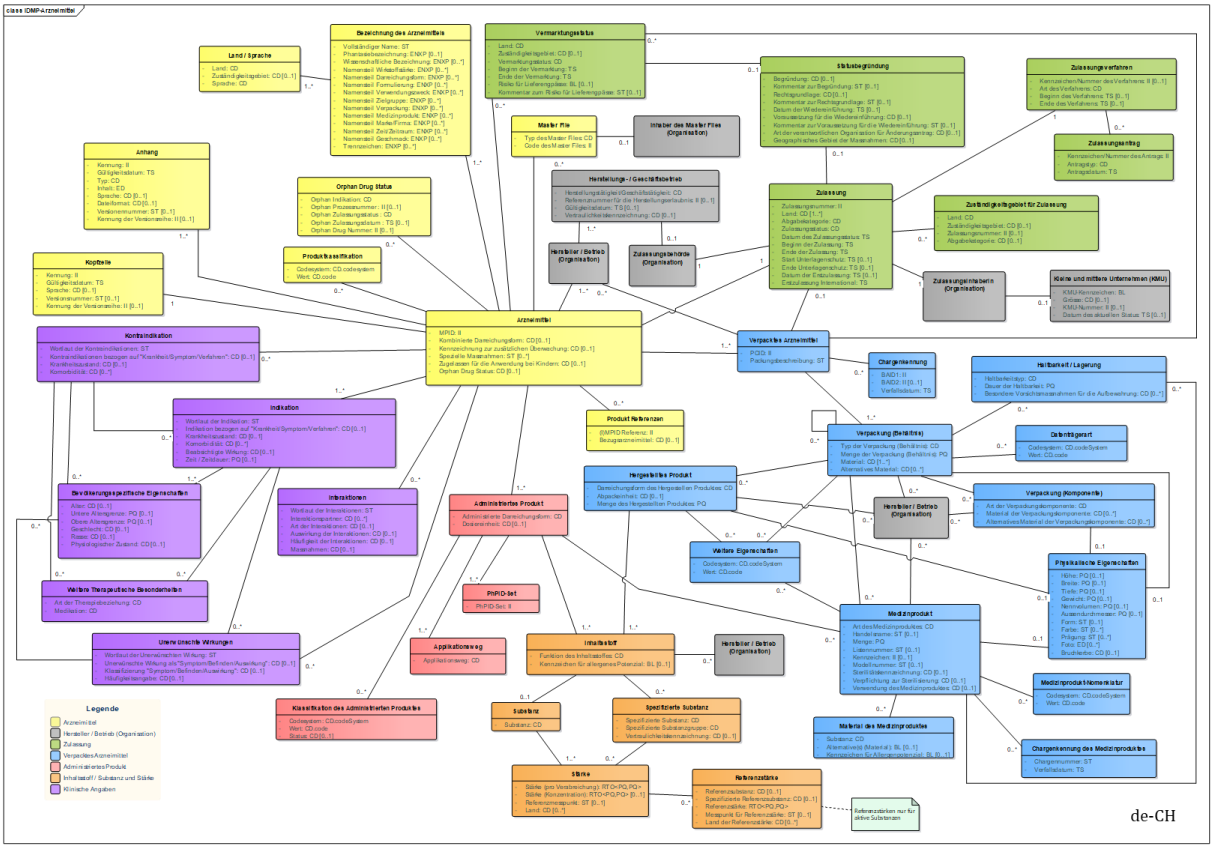
1.1 Original-Datenmodell der ISO

Das folgende Datenmodel entspricht dem Original IDMP Datenmodel der ISO gemäss ISO 11615:2017.



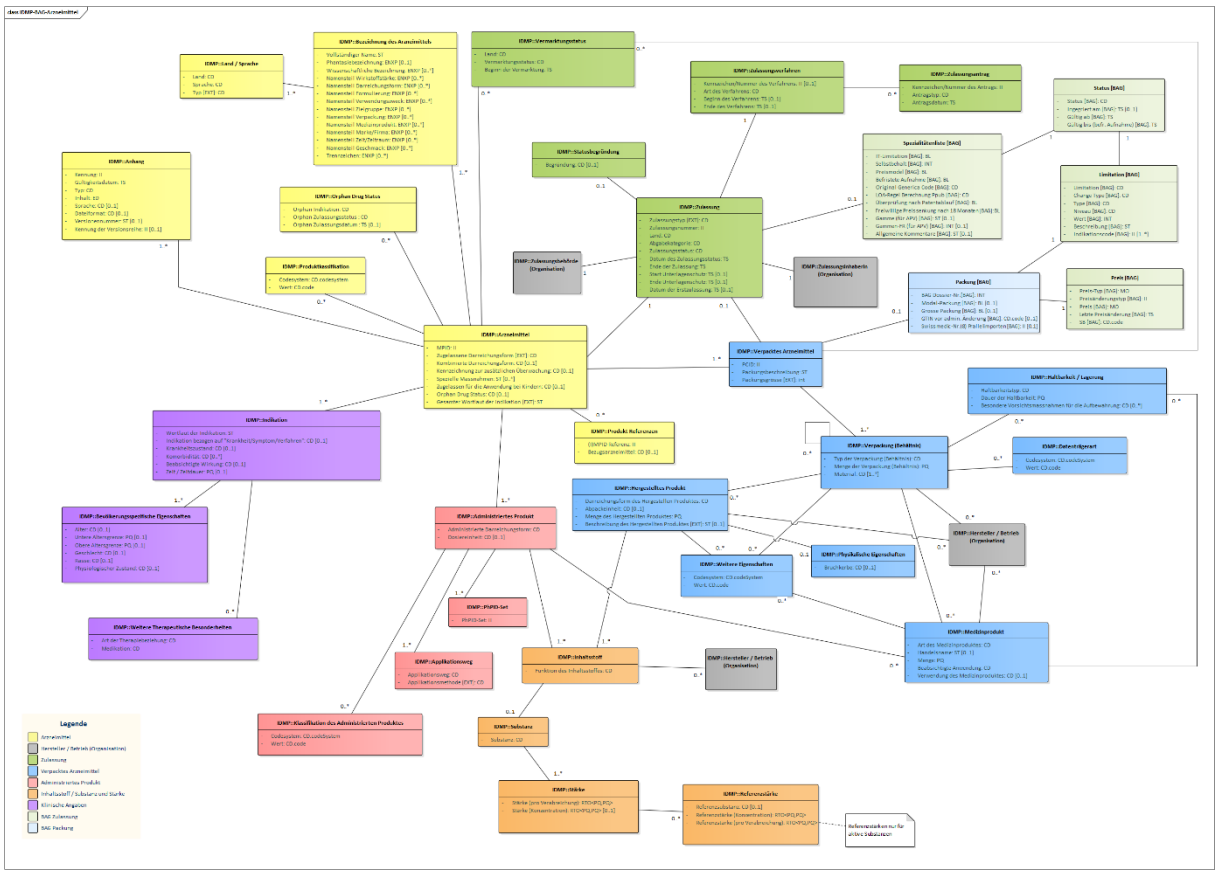
1.2 de-CH lokalisiertes ISO IDMP-Datenmodell

Das folgende Datenmodel illustriert das Original Datenmodel der ISO gemäss ISO 11615:2017 übersetzt nach Deutsch, lokalisiert für die Schweiz gemäss Amendment 1 vom ISO 11615:2017.



1.3 IDMP – BAG-SL-Datenmodell

Das folgende Datenmodel illustriert die für das BAG relevante IDMP Datenmodel erweitert mit den für die Spezialitätenliste relevanten Klassen und Attribute.



1.4 Liste der Klassen und Datenelemente – IDMP – BAG Datenmodell

In der folgenden Tabelle sind die Owner der Wertelisten, sowie die Datentypen und Kardinalitäten zu den einzelnen Elementen aufgeführt.

Data Element	Data Type	List Owner	Cardinality
Medicinal Product	Class	n/a	1..*
MPID	Identifier	n/a	1..1
Authorised Pharmaceutical Form (EXT)	Value List	EDQM	1..1
Combined Pharmaceutical Dose Form	Value List	EDQM	0..1
Additional Monitoring Indicator	Value List	Swissmedic	0..1
Special Measures	Value List	Swissmedic	0..*
Paediatric Use Indicator	Boolean	n/a	0..1
Orphan Designation Status	Boolean	n/a	0..1
Gesamter Wortlaut der Indikation (EXT)	String	n/a	1..1
Product Classification	Class	n/a	0..*
ATC	Value List	WHO	1..1
Heilmittelcode	Value List	Swissmedic	1..1
Orphan Designation	Class	n/a	0..*
Orphan Indication Type	Value List	Swissmedic	1..1
Orphan Designation Authorisation Status	Value List	Swissmedic	1..1
Orphan Designation Authorisation Date	Date	n/a	0..1
Product Name	Class	n/a	1..*
Name	String	n/a	1..1
Name Part (Type)	Value List	HL7	0..*
Country / Language			1..*
Country	Value List	ISO	1..1
Language	Value List	ISO	1..1
Product Cross-Reference	Class	n/a	0..*

I(MPID) Cross Reference	Identifier	n/a	1..1
Referenced Product Type	Value List	Swissmedic	1..1
Attached Document	Class	n/a	1..*
Identifier	Identifier	n/a	1..1
Effective Date	Date	n/a	1..1
Type	Value List	Swissmedic	1..1
Content	ED	n/a	1..1
Language	Value List	ISO	0..1
Media Type	Value List	EMA	0..1
Version Number	String	n/a	0..1
Version Set ID	Identifier	n/a	0..1
Marketing Authorisation (Medicinal Product)			1..1
Regulatory Authorisation Type	Value List	Swissmedic	1..1
Marketing Authorisation Number	Identifier	n/a	1..1
Country	Value List	ISO	1..1
Legal Status of Supply	Value List	Swissmedic	1..1
Authorisation Status	Value List	Swissmedic	1..1
Authorisation Status Date	Date	n/a	1..1
Validity Period End	Date	n/a	1..1
Data Exclusivity Start Date	Date	n/a	0..1
Data Exclusivity End Date	Date	n/a	0..1
Date of First Authorisation	Date	n/a	0..1
Spezialitätenliste (BAG) (Medicinal Product)			0..1
IT-Limitation (BAG)	Boolean	n/a	1..1
Selbstbehalt (BAG) (ehem. 20% Selbstbehalt)	Integer	n/a	0..1
Preismodell (BAG)	Boolean	n/a	0..1

Befristete Aufnahme (BAG)	Boolean	n/a	1..1
Original Generika Code (BAG)	Value List	BAG	1..1
LOA-Regel Berechnung Ppub (BAG)	Value List	BAG	1..1
Überprüfung nach Patientenlauf (BAG)	Boolean	n/a	1..1
Freiwillige Preissenkung nach 18 Monaten (BAG)	Boolean	n/a	1..1
Gamme (für APV) (BAG)	ST	n/a	0..1
Gammen-FR (für APV) (BAG)	INT	n/a	0..1
Allgemeinde Kommentare (BAG)	ST	n/a	0..1
Status (BAG) (Medicinal Product)			1..1
Status (BAG)	Value list	BAG	1..1
Integriert am (BAG)	Date	n/a	0..1
Gültig ab (BAG)	Date	n/a	1..1
Gültig bis (befr. Aufnahme) (BAG)	Date	n/a	1..1
Status Reason (Marketing Authorisation)			0..1
Reason	Value List	Swissmedic	0..1
Marketing Authorisation Procedure (Medicinal Product)			1..1
Procedure Type	Value List	Swissmedic	1..1
Procedure Identifier/Number	Identifier	n/a	0..1
Procedure Date Start	Date	n/a	0..1
Procedure Date End	Date	n/a	0..1
Marketing Authorisation Application (Medicinal Product)			0..*
Application Identifier/Number	Identifier	n/a	1..1

Application Type	Value List	Swissmedic	1..1
Application Date	Date	n/a	1..1
Marketing Authorisation Holder			1..1
Name	Address	n/a	1..1
GLN	Identifier	n/a	1..1
Medicines Regulatory Agency			1..1
Name	Address	n/a	1..1
GLN	Identifier	n/a	1..1
Packaged Medicinal Product			1..*
PCID	Identifier	n/a	1..1
Package Description	String	n/a	1..1
Pack Size (EXT)	Physical Quantity [number, unit]	EDQM [Unit]	0..1
Data Carrier Identifier			0..*
ID Code System	Value List	GS1	1..1
GTIN	Identifier	n/a	1..1
Packaged Item			1..*
Package Item (Container) Type	Value List	EDQM	1..1
Package Item (Container) Quantity	Physical Quantity [number]	n/a	1..1
Material	Value List	EMA	1..*
Manufactured Item Quantity	Physical Quantity [number, unit]	UCUM [Unit]	1..1
Other Characteristics (Package Item)			0..*
Code System/Value	Value List	Swissmedic	1..1
Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	Identifier	n/a	1..1
Legal Status of Supply	Value List	Swissmedic	1..1
Authorisation Status	Value Liste	Swissmedic	1..1

Authorisation Status Date	Date	n/a	1..1
Validity Period End	Date	n/a	1..1
Marketing Status (Packaged Medicinal Product)			0..*
Marketing Status	Value List	Swissmedic	1..1
Marketing Date Start	Date	n/a	1..1
Packung (BAG) (Packaged Medicinal Product)			0..1
BAG Dossier-Nr. (BAG)	Integer	n/a	1..1
Modal Packung (BAG)	Boolean	n/a	0..1
Grosse Packung (BAG)	Boolean	n/a	0..1
GTIN vor admin. Änderung (BAG)	Value List	BAG	0..1
Swissmedic Nr. (8) Parallelimporten (BAG)	Identifier	n/a	0..1
Limitation (BAG) (Packaged Medicinal Product)			1..1
Limitation (BAG)	Value List	BAG	1..1
Change Type (BAG)	Value List	BAG	1..1
Type (BAG)	Value List	BAG	1..1
Niveau (BAG)	Value List	BAG	1..1
Wert (BAG)	Integer	n/a	1..1
Beschreibung (BAG)	String	n/a	1..1
Indikationscode (BAG)	Identifier	n/a	1..*
Status (BAG) (Medicinal Product)			1..1
Status (BAG)	Value List	BAG	1..1
Integriert am (BAG)	Date	n/a	0..1
Gültig ab (BAG)	Date	n/a	1..1
Gültig bis (befr. Aufnahme) (BAG)	Date	n/a	1..1

Preis (BAG) (Packaged Medicinal Product)			1..1
Preis-Typ (BAG)	Value List	n/a	1..1
Preisänderungstyp (BAG)	Value List	BAG	1..1
Preis (BAG)	Money	n/a	1..1
Letzte Preisänderung (BAG)	Date	n/a	0..1
Shelf Life / Storage			0..*
Shelf Life Type	Value List	EMA	1..1
Shelf Life Time Period	Physical Quantity	UCUM [Unit]	1..1
Special Precautions of Storage	Value List	Swissmedic	0..*
Physical Characteristics			0..*
Scoring	Value List	Swissmedic	0..1
Manufactured Item			0..*
Manufactured Dose Form	Value List	EDQM	1..1
Unit of Presentation	Value List	EDQM	0..1
Description	String	n/a	0..1
Ingredient (Manufactured Item)			1..*
Ingredient Role	Value List	Swissmedic	1..1
Substance			1..1
Substance	Value List	GSRS (UNII) [WHO ab 2025]	1..1
Strength			1..1
Quantity Operator	Value List	EMA	1..1
Strength (presentation)	Physical Quantity	EDQM UCUM	1..1
Strength (concentration)	Physical Quantity	UCUM	0..1
Reference Strength			0..*
Reference Substance	Value List	GSRS (UNII) [WHO ab 2025]	1..1
Quantity Operator	Value List	EMA	1..1
Reference Strength	Physical Quantity	EDQM	1..1

		UCUM	
Pharmaceutical Product			1..*
Administrable Dose Form	Value List	EDQM	1..1
Unit of Presentation	Value List	EDQM	0..1
Route of Administration			1..*
Route of Administration	Value List	EDQM	1..1
Methode of Administration	Value List	EMA	0..1
Ingredient (Pharmaceutical Product)			
Ingredient Role	Value List	Swissmedic	1..1
Substance			1..1
Substance	Value List	GSRS (UNII) [WHO ab 2025]	1..1
Manufacturer (Substance)			0..*
Name	Address	n/a	1..1
GLN	Identifier	n/a	1..1
Confidentiality Indicator	Value List	EMA	1..1
Strength			1..1
Quantity Operator	Value List	EMA	1..1
Strength (presentation)	Physical Quantity	EDQM UCUM	1..1
Strength (concentration)	Physical Quantity	UCUM	0..1
Reference Strength			0..*
Reference Substance	Value List	GSRS (UNII) [WHO ab 2025]	1..1
Quantity Operator	Value List	EMA	1..1
Reference Strength	Physical Quantity	EDQM UCUM	1..1
Therapeutic Indication			1..*
Indication as	Value List	MSSO	1..1
Comorbidity	Value List	MSSO	1..1
Intended Effect	Value List	EMA	1..1
Population Specifics			1..*
Age	Value List	EMA	0..1

Age Range Low	Physical Quantity	UCUM	0..1
Age Range High	Physical Quantity	UCUM	0..1
Gender	Value List	EMA	0..1
Race	Value List	EMA	0..1
Physiological Condition	Value List	EMA	0..1
Other Therapy Specifics			0..*
Therapy Relationship Type	Value List	EMA	1..1
Medication	Value List	EMA	1..1

IDMP Element	Example Code	List Owner
Medicinal Product		
MPID	CH-7601007957330-5603801	Swissmedic
Domain	HAM	Swissmedic
Authorised Pharmaceutical Form	VAGI	Swissmedic
Product Classification		
ATC	G02BB01	WHO
Heilmittelcode	Synthetica Human	Swissmedic
Country / Language		
Language	fr	ISO
Marketing Authorisation (Medicinal Product)		
Marketing Authorisation Number	5603802	Swissmedic
Legal Status of Supply	B	Swissmedic
Authorisation Status	Z	Swissmedic
Marketing Authorisation Holder		
GLN	7601007957330	GS1
Packaged Medicinal Product		
PCID	CH-7601007957330-5603801-002	Swissmedic
Data Carrier Identifier		

GTIN	7680560380021	GS1
Packaged Item		
Package Item (Container) Quantity	1 Box	Unit: EDQM
Packaged Item		
Manufactured Item Quantity	1 System / box 1 System / sachet	Numerator Unit: EDQM Denominator Unit: EDQM
Marketing Authorisation (Packaged Medicinal Product)		
Legal Status of Supply	B	Swissmedic
Authorisation Number	29550001	Swissmedic
Authorisation Status	Z	Swissmedic
Shelf Life / Storage		
Shelf Life Type	100000073403	EMA
Shelf Life Time Period	40 mt	Unit: UCUM
Special Precautions of Storage	100000073414	EMA
Device Nomenclature		
Value	IIb	EMA
Manufactured Item		
Manufactured Dose Form	10915000	EDQM
Unit of Presentation	15053000	EDQM
Ingredient (Manufactured Item)		
Ingredient Role	Active	Swissmedic
Substance	304GTH6RNH	UNII
Strength (presentation)	11.7 mg / System 11.7 mg / Ring	Numerator Unit: UCUM Denominator Unit: EDQM
Strength (concentration)	0.005 mg / h 0.12 mg / 24 h	Numerator Unit: UCUM Denominator Unit: UCUM
Pharmaceutical Product		
Administrable Dose Form	10915000	EDQM
Unit of Presentation	15053000	EDQM

Route of Administration	20072000	EDQM
Methode of Administration	200000002039	EMA
Ingredient (Pharmaceutical Product)		
Ingredient Role	Active	Swissmedic
Substance	304GTH6RNH	UNII
Strength (presentation)	11.7 mg / System 11.7 mg / Ring	Numerator Unit: UCUM Denominator Unit: EDQM
Strength (concentration)	0.005 mg / h 0.12 mg / 24 h	Numerator Unit: UCUM Denominator Unit: UCUM
Therapeutic Indication		
Indication as	10073728	MSSO
Comorbidity	10027308	MSSO
Intended Effect	200000003194	EMA

2 Datenbeispiele

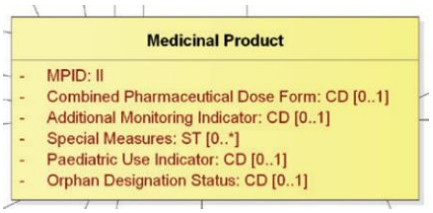
In diesem Kapitel sind diverse Beispielprodukte basierend auf dem IDMP-BAG-SL-Datenmodel aufgebaut. Das Kapitel enthält die folgenden Beispielprodukte:

Beispielprodukt	Produktmerkmale	Verpackungsmerkmale
Cuprior		
Entocort Enema	Klistier Lösung	
Estalis	Pflaster	
Keytruda		
Paxlovid		2 Wirkstoffe separat in einer Packung
Triogen	Gleiche aktive Substanz, anderes Salz (siehe Cuprior)	

2.1 CUPRIOR Filmtabl 150 mg 72 Stk

Cuprior, Filmtabletten	
Image	

Quelle		
Compendium	CUPRIOR Filmtabl 150 mg	compendium.ch®
SAI	CUPRIOR Filmtabl 150 mg 72 Stk	refdata

Medicinal Product			
MPID	CH-7640109110007-6771901		
Approved Dose Form (EXT)	FILM	Filmtabletten	

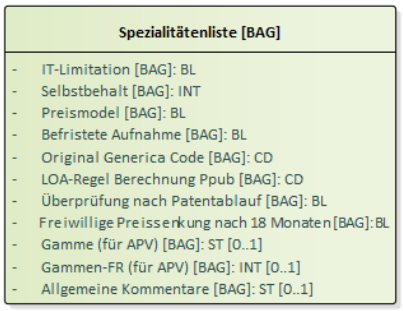
Product Classification		
ATC	A16AX12	
Heilmittelcode	S – Synthetika	

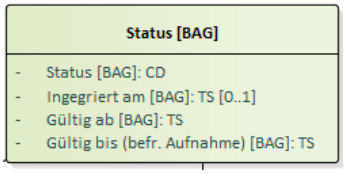
Medicinal Product Name		
Type (EXT)	Original	
Full Name	Cuprior 150 mg, Filmtabletten	
Invented Name Part	Cuprior	
Pharmaceutical Dose Form Part	Filmtabletten	
Strength Part	150 mg	
Delimiter	,	
Country / Language		

Language	de	Deutsch	

Medicinal Product Name			
Type (EXT)	BAG		
Full Name	CUPRIOR Filmtabl 150 mg		
Invented Name Part	CUPRIOR		
Pharmaceutical Dose Form Part	Filmtabl		
Strength Part	150 mg		
Country / Language			
Language	de	Deutsch	

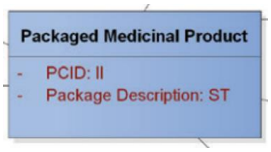
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	6771901		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	21.01.2021		
Validity Period End	20.01.2026		
Date of First Authorisation	21.01.2021		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	-		

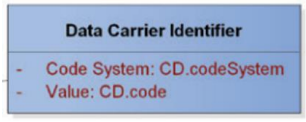
Original Generika Code (BAG)	-	
BAG Dossier-Nr. (BAG)	21208	

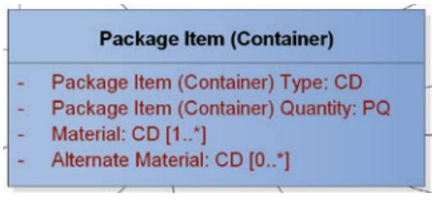
Status (BAG) (Medicinal Product)		
Integriert am (BAG)	01.08.2021	
gültig ab (BAG)	01.08.2021	
gültig bis (befr. Aufnahme) (BAG)	31.12.9999	

Marketing Authorisation Holder (Organisation)		
Name	Curatis AG	
GLN	7640109110007	

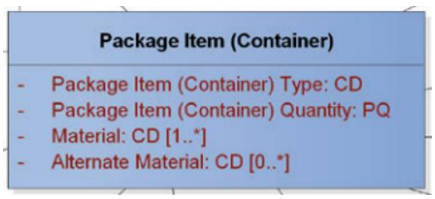
Hinweis: Pack Size, 72 Filmtabletten

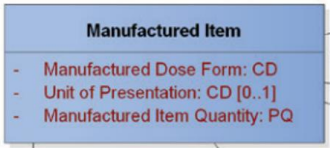
Packaged Medicinal Product		
PCID	CH-7640109110007-6771901-001	
Package Description	CUPRIOR Filmtabl 150 mg 72 Stk	
Pack Size (EXT)	72 Tablette(n)	

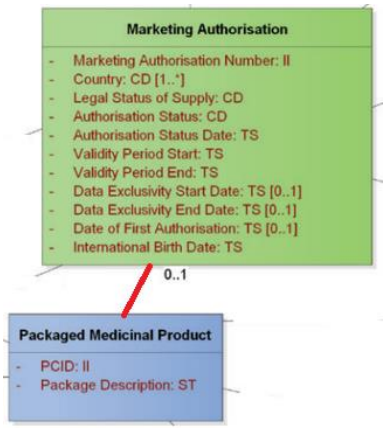
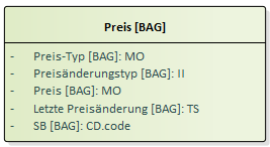
Data Carrier Identifier		
GTIN (Code System)	7680677190018	

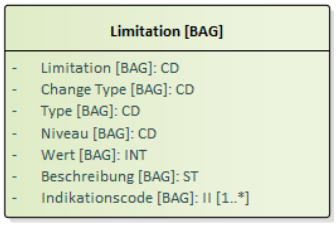
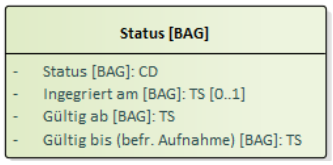
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		

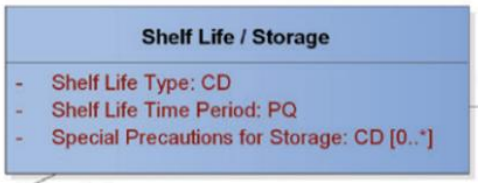
Material	Karton		

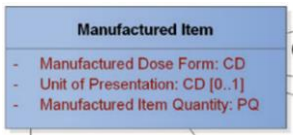
Packaged Item (Container)			
Package Item (Container) Type	30007000	Blister	
Package Item (Container) Quantity	Unknown		
Material	Aluminium, Aluminium		

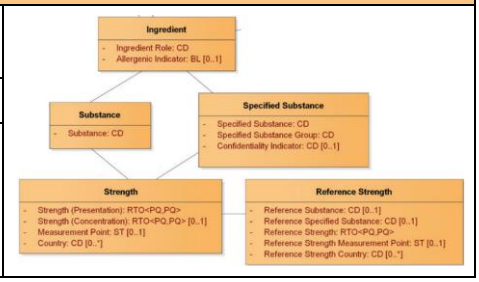
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	72	Tabletten (per box)	

Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Type	tbd		
Marketing Authorisation Number	67719001		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	21.01.2021		
Validity Period End	20.01.2026		
Preis (BAG) (Packaged Medicinal Product)			
FAP (BAG)	CHF 3022.28		
PP (BAG)	CHF 3343.85		
Preis-änderungstyp (BAG)	Preisänderung nach 3-jährlicher Überprüfung der Aufnahmebedingungen		

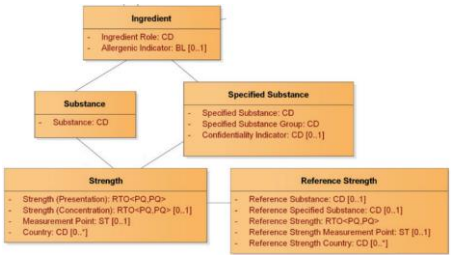
Limitation (BAG) (Packaged Medicinal Product)		
Limitation (BAG)	L	
Beschreibung (BAG)	xxx	
Status (BAG) (Packaged Medicinal Product)		
Gültig ab (BAG)	01.08.2021	
Gültig bis (BAG)	31.12.9999	

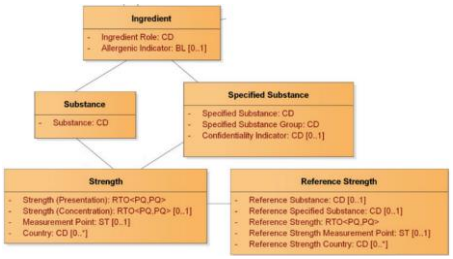
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	24 mo		
Special Precautions of Storage	NO30	Nicht über 30°C lagern	

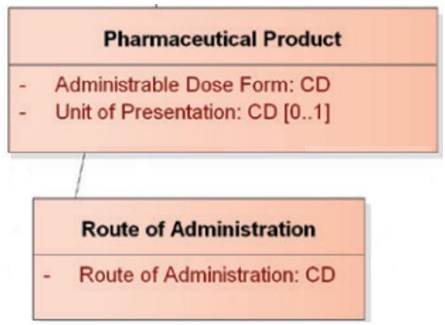
Manufactured Item			
Manufactured Dose Form	10221000	Filmtablette	
Unit of Presentation	15054000	Tablette	

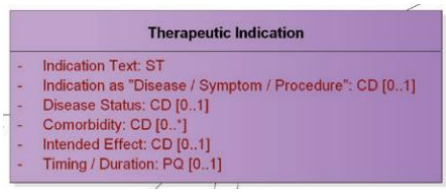
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	SJ76Y07H5F	Trientinum	
Strength (presentation)	150 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	

Substance		Trientini tetrahydrochloridum	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	3OWL53L36A	Mannitolum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	R8WTH25YS2	Glyceroli dibehenas	
	532B59J990	Poly (alcohol vinylicus)	
	7SEV7J4R1U	Talc Talcum	
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171	
	HYE7O27HAO	Glyceroli monocaprylocapras	
	EX438O2MRT	E 172 (flavum) YELLOW LAKE CLF 3076 (E104 AND E172)	
	368GB5141J	Natrii laurilsulfas	
	9NEZ333N27	0.057 mg Natrium	

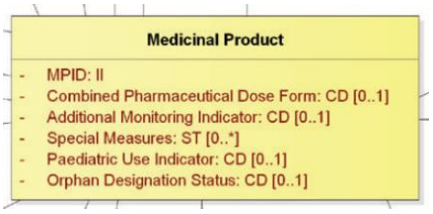
Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10221000	Filmtablette	
Unit of Presentation	15054000	Tablet	
Route of Administration	20053000	Oral use	
Methode of Administration (Swissmedic)	200000002052	Swallowing	

Therapeutic Indication			
Indication as	10061091	Copper metabolism disorder (Morbus Wilson)	
Intended Effect	200000003194	Therapie	

2.2 ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk

Entocort Enema, Klistier Lösung + Tabletten	
Image	

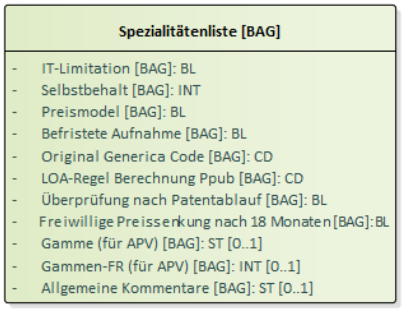
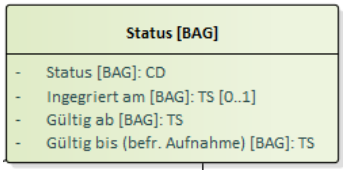
Quelle		
Compendium	ENTOCORT Enema Klistier Lösung + Tabletten	compendium.ch®
SAI	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	refdata

Medicinal Product			
MPID	CH-7601001346451-5204201		
Approved Dose Form (EXT)	TABLR	Tabletten und Lösungsmittel zur Herstellung einer Rektalsuspension	

Product Classification		
ATC (Code System)	A07EA06	
Heilmittelcode (Value)	S – Synthetika	

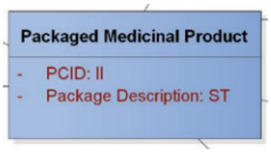
Medicinal Product Name			
Type (EXT)	Original		
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk		
Invented Name Part	ENTOCORT Enema		
Pharmaceutical Dose Form Part	Klistier Lösung + Tabletten		
Container or Pack Part	7 Stk		
Delimiter Part	,		
Country / Language			
Language	de	Deutsch	

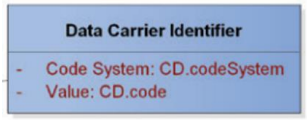
Medicinal Product Name			
Type (EXT)	BAG		
Full Name	ENTOCORT Enema Klistier Lösung + Tabletten		
Invented Name Part	ENTOCORT Enema		
Pharmaceutical Dose Form Part	Klistier Lösung + Tabletten		
Country / Language			
Language	de	Deutsch	

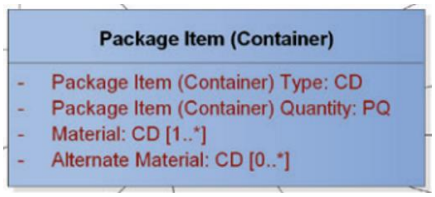
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	5204201		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	18.06.1993		
Validity Period End	31.12.9999		
Date of First Authorisation	18.06.1993		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	-		
Original Generika Code (BAG)	-		
BAG Dossier-Nr. (BAG)	17973		
Status (BAG) (Medicinal Product)			
Integriert am (BAG)	01.02.2004		
gültig ab (BAG)	01.02.2004		
gültig bis (befr. Aufnahme) (BAG)	31.12.9999		

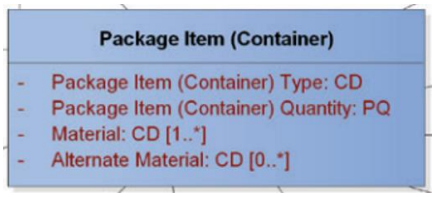
Marketing Authorisation Holder (Organisation)		
Name	Tillotts Pharma AG	
GLN	7601001346451	

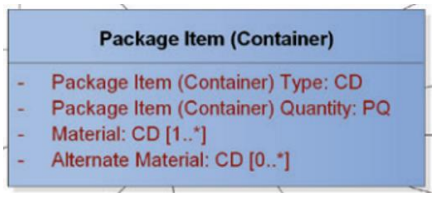
Hinweis: Pack Size, Tablette und Lösungsmittel für Klistier Lösung

Packaged Medicinal Product		
PCID	CH-7601001346451-5204201-011	
Package Description	ENTOCORT Enema Klistier Lösung + Tabletten 7 Stk	
Pack Size (EXT)	7 Lösung 7 Tablette	

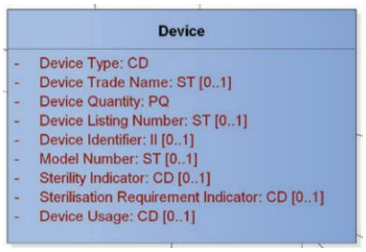
Data Carrier Identifier		
GTIN (Code System)	7680520420118	

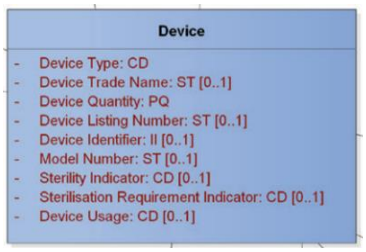
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

Packaged Item (Container)			
Package Item (Container) Type	30007000	Blister	
Package Item (Container) Quantity	5		
Material	Aluminium, Aluminium		

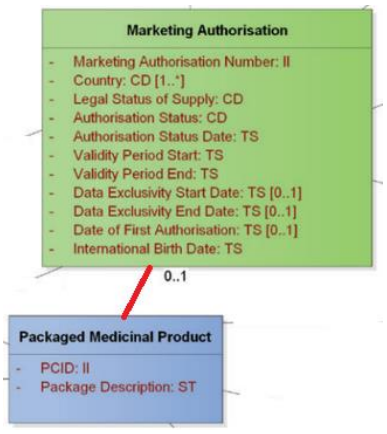
Packaged Item (Container)			
Package Item (Container) Type	30008000	Bottle	
Package Item (Container) Quantity	7		
Material	200000003214	Polyethylen	

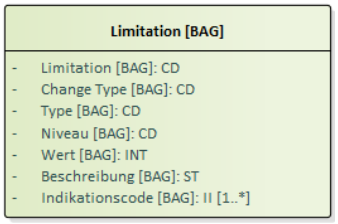
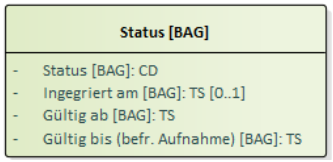
Package (Component)			
Component Type	30013000	Cap	
Component Materila	200000003214	Polyethylen	

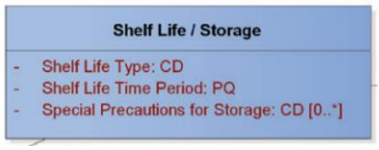
Device			
Device Type	30012000	Rektalkanüle (Applikator Enema)	
Device Quantity	7		

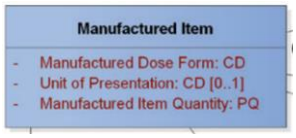
Device			
Device Type	tbd	Plastikhandschutz	
Device Quantity	7		

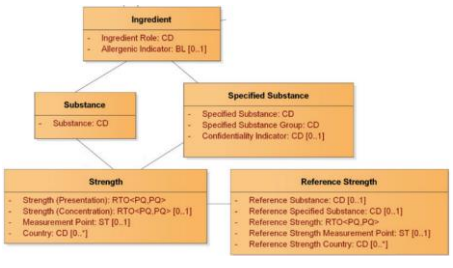
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	7	Tabletten (per blister)	
Manufactured Item Quantity	7	Lösungsmittel (per box)	

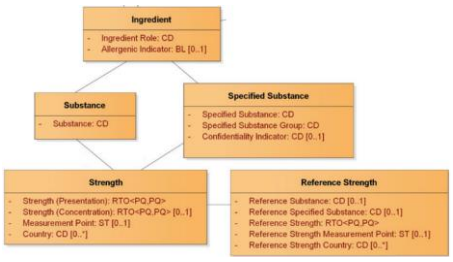
Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	52042011		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	18.06.1993		

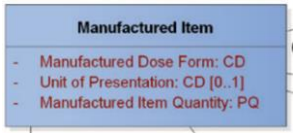
Preis (BAG) (Packaged Medicinal Product)		
FAP (BAG)	CHF 40.89	
PP (BAG)	CHF 63.35	
Preis-änderungstyp (BAG)	Preisänderung nach 3-jährlicher Überprüfung der Aufnahmebedingungen	
Limitation (BAG) (Packaged Medicinal Product)		
Limitation (BAG)	L	
Beschreibung (BAG)	xxx	
Status (BAG) (Packaged Medicinal Product)		
Gültig ab (BAG)	01.01.2007	
Gültig bis (BAG)	31.12.9999	

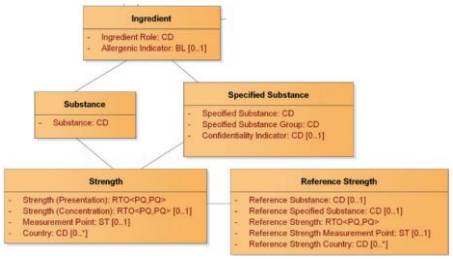
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	60 mo		
Special Precautions of Storage	NO30	Nicht über 30°C lagern	

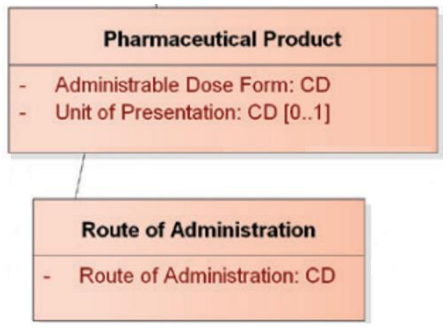
Manufactured Item			
Manufactured Dose Form	11012000	Tablet for rectal suspension	
Unit of Presentation	15054000	Tablette	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	Q3OKS62Q6X	Budesonidum	
Strength (presentation)	2.3 mg (per UoP)		

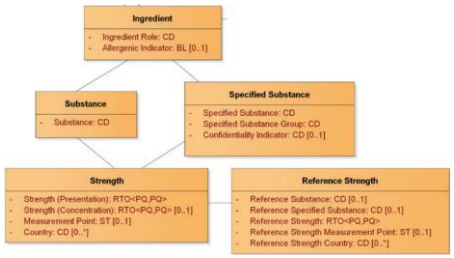
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	

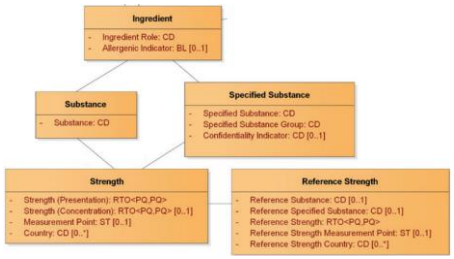
Manufactured Item			
Manufactured Dose Form	13035000	Lösungsmittel	
Unit of Presentation	15009000	Bottle	

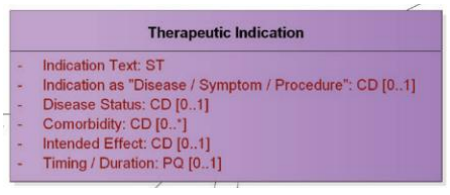
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11006000	Rectal suspension	
Unit of Presentation	15009000	Bottle	
Route of Administration	20061000	Rectal use	
Methode of Administration (Swissmedic)	200000002039	Application	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	Q3OKS62Q6X	Budesonidum	

Strength (presentation)	2.0 mg (per UoP)	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	3SY5LH9PMK	Lactosum	
	957E53WV42	Riboflavini natrii phosphas	
	2S7830E561	Crospovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	70097M6I30	Magnesii stearas	
	A2I8C7HI9T	METHYLPARABEN E 218	
	Z8IX2SC1OH	Propylis parahydroxybenzoas	
	451W47IQ8X	Natrii chloridum	
	059QF0KO0R	Aqua purificata	

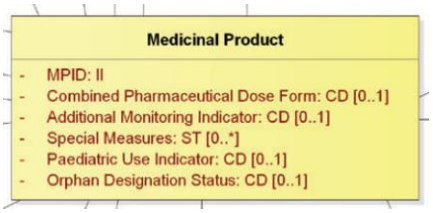
Therapeutic Indication			
Indication Text	Leichte bis mittelschwere Colitis ulcerosa des Rectums sowie des Colon sigmoideum		
Indication as	10009900	Colitis ulcerative	
Intended Effect	200000003194	Therapie	

2.3 ESTALIS Matrixpfl 50/250

Estalis, transdermale Pflaster	
Image	

Quelle		
Compendium	ESTALIS Matrixpfl 50/250	compendium.ch®
SAI	ESTALIS Matrixpfl 50/250 8 Stk ESTALIS Matrixpfl 50/250 24 Stk	refdata

Medicinal Product			
MPID	CH-7601001029439-5470402		
Approved Dose Form (EXT)	TRAP	Transdermales Pflaster	



Product Classification	
ATC (Code System)	G03FA01
Heilmittelcode (Value)	S – Synthetika

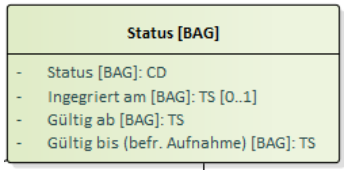
Medicinal Product Name			
TYPE (EXT)	Original		
Full Name	ESTALIS Matrixpfl 50/250 8 Stk		
Invented Name Part	ESTALIS		
Strength Part	50/250		
Pharmaceutical Dose Form Part	Matrixpfl		
Container or Pack Part	8 Stk		
Country / Language			
Language	de	Deutsch	

Medicinal Product Name			
TYPE (EXT)	Original		
Full Name	ESTALIS Matrixpfl 50/250 24 Stk		
Invented Name Part	ESTALIS		
Strength Part	50/250		
Pharmaceutical Dose Form Part	Matrixpfl		
Container or Pack Part	24 Stk		
Country / Language			
Language	de	Deutsch	

Medicinal Product Name		
Type (EXT)	BAG	
Full Name	ESTALIS Matrixpfl 50/250	
Invented Name Part	ESTALIS	
Strength Part	50/250	

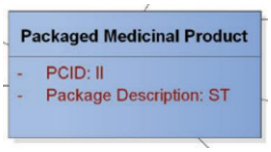
Pharmaceutical Dose Form Part	Matrixpfl		
Country / Language			
Language	de	Deutsch	

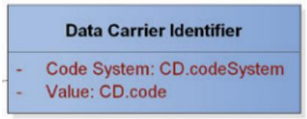
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	5470402		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	17.08.1999		
Validity Period End	31.12.9999		
Date of First Authorisation	17.08.1999		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	-		
Original Generika Code (BAG)	-		
BAG Dossier-Nr. (BAG)	17418		
Status (BAG) (Medicinal Product)			

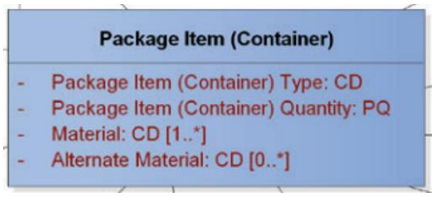
Integriert am (BAG)	15.04.2000	
gültig ab (BAG)	15.04.2000	
gültig bis (befr. Aufnahme) (BAG)	31.12.9999	

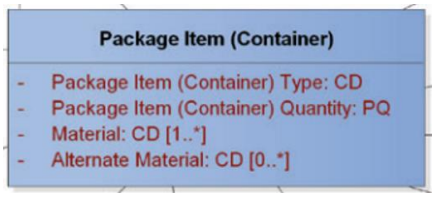
Marketing Authorisation Holder (Organisation)		
Name	Sandoz Pharmaceuticals AG	
GLN	7601001029439	

Hinweis: Pack Size, 8 Pflaster. *Mehrere Packungsgrössen werden wie folgt separat erfasst*

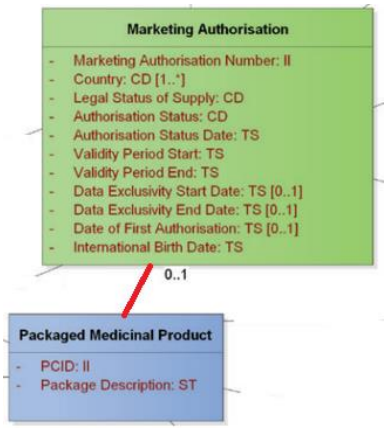
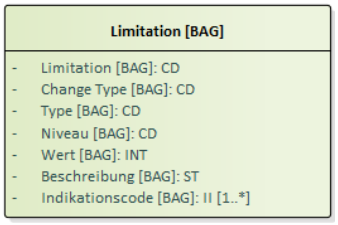
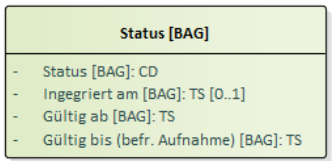
Packaged Medicinal Product		
PCID	CH-7601001029439-5470402-089	
Package Description	ESTALIS Matrixpfl 50/250 8 Stk	
Pack Size (EXT)	8 Pflaster	

Data Carrier Identifier		
GTIN (Code System)	7680547040894	

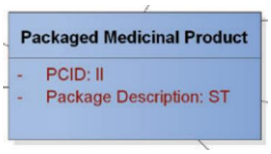
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

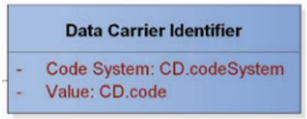
Packaged Item (Container)			
Package Item (Container) Type	30054000	Sachet	
Package Item (Container) Quantity	8		
Material	Unknown		

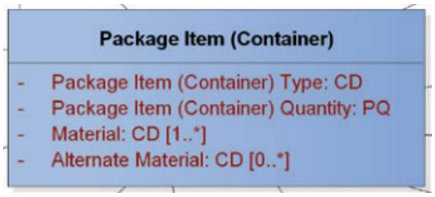
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	1	Patches (per Sachet)	

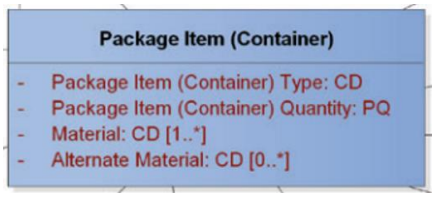
Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	54704089		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	17.08.1999		
Preis (BAG) (Packaged Medicinal Product)			
FAP (BAG)	CHF 11.63		
PP (BAG)	CHF 25.65		
Preis-änderungstyp (BAG)	Auslandspreisvergleich		
Limitation (BAG) (Packaged Medicinal Product)			
Limitation (BAG)	-		
Beschreibung (BAG)	xxx		
Status (BAG) (Packaged Medicinal Product)			
Gültig ab (BAG)	xxx		
Gültig bis (BAG)	xxx		

Hinweis: Pack Size, 24 Pflaster. *Mehrere Packungsgrössen werden wie folgt separat erfasst.*

Packaged Medicinal Product		
PCID	CH-7601001029439-5470402-097	
Package Description	ESTALIS Matrixpfl 50/250 24 Stk	
Pack Size (EXT)	24 Pflaster	

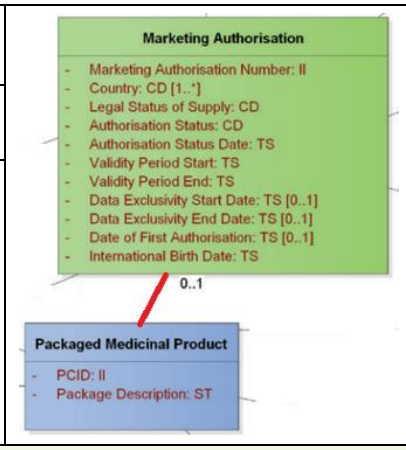
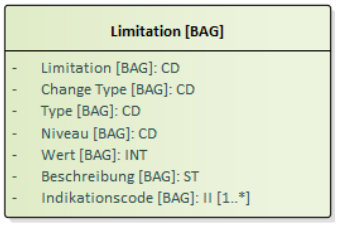
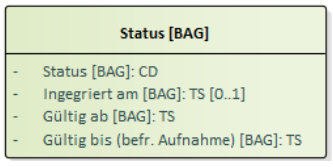
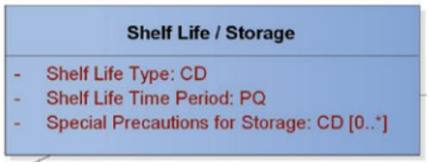
Data Carrier Identifier		
GTIN (Code System)	7680547040979	

Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

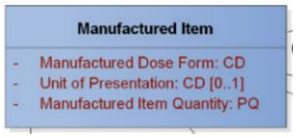
Packaged Item (Container)			
Package Item (Container) Type	30054000	Sachet	
Package Item (Container) Quantity	24		
Material	Unknown		

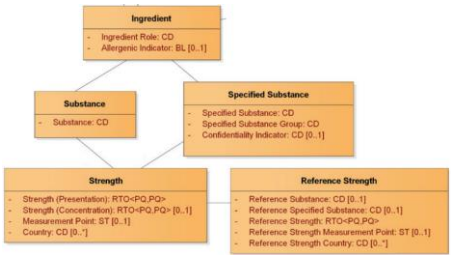
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	1	Patch (per Sachet)	

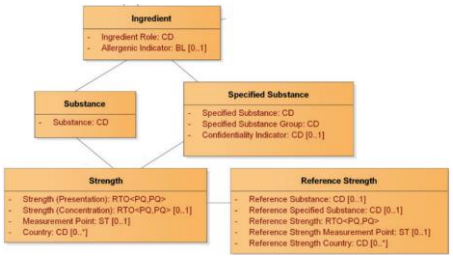
Marketing Authorisation (Packaged Medicinal Product)		
Marketing Authorisation Number	54704097	

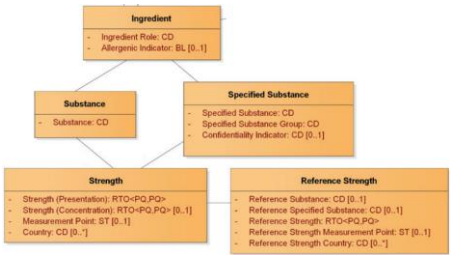
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	17.08.1999		
Preis (BAG) (Packaged Medicinal Product)			
FAP (BAG)	CHF 32.44		
PP (BAG)	CHF 53.65		
Preis-änderungstyp (BAG)	Auslandspreisvergleich		
Limitation (BAG) (Packaged Medicinal Product)			
Limitation (BAG)	-		
Beschreibung (BAG)	xxx		
Status (BAG) (Packaged Medicinal Product)			
Gültig ab (BAG)	xxx		
Gültig bis (BAG)	xxx		
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	6 mo		
Special Precautions of Storage	NO25	Nicht über 25°C	
	L	vor Licht Schützen	

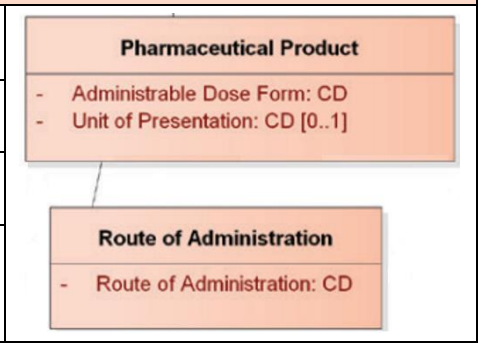
	2	Im Kühlschrank (2°C - 8°C)	

Manufactured Item			
Manufactured Dose Form	10519000	Transdermal patch	
Unit of Presentation	15036000	Patch	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	CXY7B3Q98Z	Estradiolum hemihydricum	
Strength (presentation)	0.512 mg (per UoP)		
Reference Substance	ENB39R14VF	Estradiol	
Reference Strength	0.496 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	9S44LIC7OJ	Norethisteroni acetas	
Strength (presentation)	4.8 mg (per UoP)		
Reference Substance	T18F433X4S	Norethisteronum	
Reference Strength	4.2073 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	83D19O7250	Silicone adhesive	
	180M9K3GHP	acrylic adhesive	
	U725QWY32X	povidonum K 30	
	2UMI9U37CP	acidum oleicum	
	E107L85C40	dipropylenglycolum	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10519000	Transdermales Pflaster	
Unit of Presentation	15036000	Pflaster	
Route of Administration	20070000	Transdermale Anwendung	
Methode of Administration (Swissmedic)	200000002039	Application	

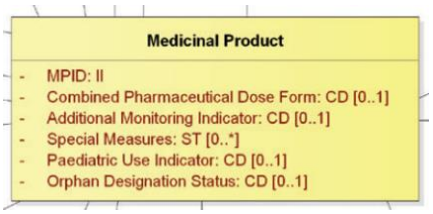
Therapeutic Indication			
Indication as	10030247	Oestrogenmangel	
Comorbidity	10027308	Menopause	
Intended Effect	200000003192	Prophylaxis	

Therapeutic Indication			
Indication as	10031285	Osteoporose postmenopausal	
Intended Effect	200000003194	Therapy	
Intended Effect	200000003192	Prophylaxis	

2.4 KEYTRUDA Inf Konz 100 mg/4ml Durchstf

Keytruda, Konzentrat zur Herstellung einer Infusionslösung	
Image	

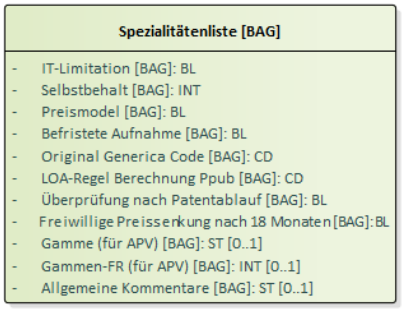
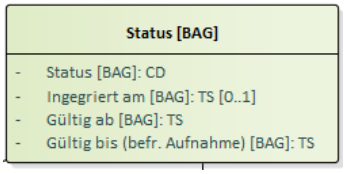
Quelle		
Compendium	Keytruda Inf Konz 100 mg/4ml	compendium.ch®
SAI	KEYTRUDA Inf Konz 100 mg/4ml Durchstf	refdata

Medicinal Product			
MPID	CH-7601001001138-6623101		
Approved Dose Form (EXT)	KOINF	Konzentrat zur Herstellung einer Infusionslösung	

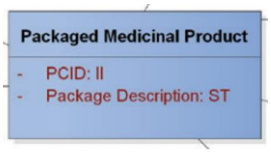
Product Classification		
ATC (Code System)	L01FF02	
Heilmittelcode (Value)	BT – Biotechnologika	

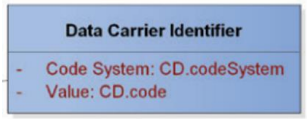
Medicinal Product Name			
Type (EXT)	Original		
Full Name	KEYTRUDA Inf Konz 100 mg/4ml Durchstf		
Invented Name Part	KEYTRUDA		
Strength Part	100 mg/4ml		
Pharmaceutical Dose Form Part	Inf Konz		
Container or Pack Part	Durchstf		
Country / Language			
Language	de	Deutsch	

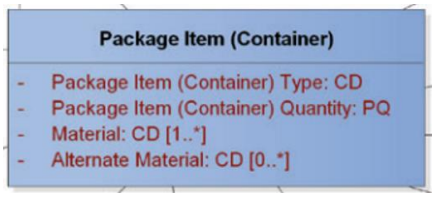
Medicinal Product Name			
Type (EXT)	BAG		
Full Name	KEYTRUDA Inf Konz 100 mg/4ml		
Invented Name Part	KEYTRUDA		
Strength Part	100 mg/4ml		
Pharmaceutical Dose Form Part	Inf Konz		
Country / Language			
Language	de	Deutsch	

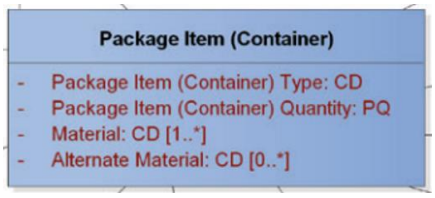
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	6623101		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	22.02.2017		
Validity Period End	31.12.9999		
Date of First Authorisation	22.02.2017		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	PM		
Original Generika Code (BAG)	-		
BAG Dossier-Nr. (BAG)	20416		
Status (BAG) (Medicinal Product)			
Integriert am (BAG)	01.09.2017		
gültig ab (BAG)	01.01.2023		
gültig bis (befr. Aufnahme) (BAG)	31.12.2024		

Marketing Authorisation Holder (Organisation)		
Name	MSD Merck Sharp & Dohme AG	
GLN	7601001001138	

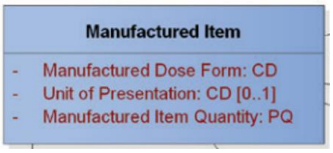
Hinweis: Pack Size, 1 Durchstechflasche.		
Packaged Medicinal Product		
PCID	CH-7601001001138-6623101-001	
Package Description	KEYTRUDA Inf Konz 100 mg/4ml Durchstf	
Pack Size (EXT)	1 Durchstechflasche(n)	

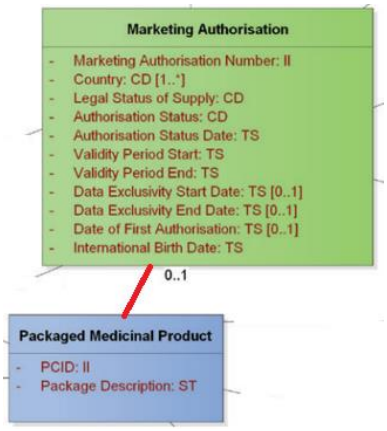
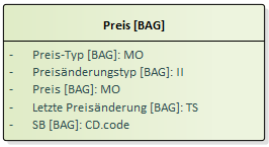
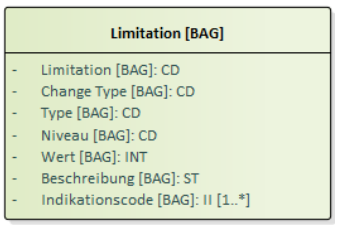
Data Carrier Identifier		
GTIN (Code System)	7680662310018	

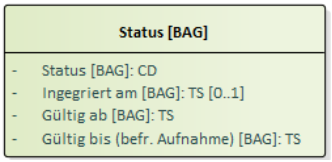
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

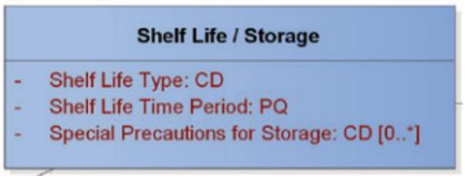
Packaged Item (Container)			
Package Item (Container) Type	30069000	Vial	
Package Item (Container) Quantity	1		
Material	Glas		

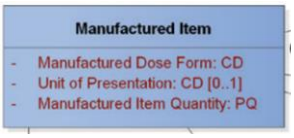
Package (Component)			
Component Type	30064000	Stopper	
Component Material	200000003200	Aluminium,	
	200000003226	Rubber	

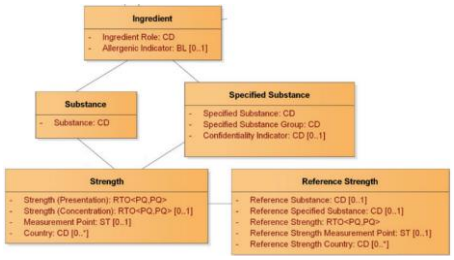
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	4	ml	

Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	66231001		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	22.02.2017		
Preis (BAG) (Packaged Medicinal Product)			
FAP (BAG)	CHF 4407.68		
PP (BAG)	CHF 4763.85		
Preis-änderungstyp (BAG)	Normale Preismutation		
Limitation (BAG) (Packaged Medicinal Product)			
Limitation (BAG)	L		
Beschreibung (BAG)	xxx		
Status (BAG) (Packaged Medicinal Product)			
Gültig ab (BAG)	01.09.2017		

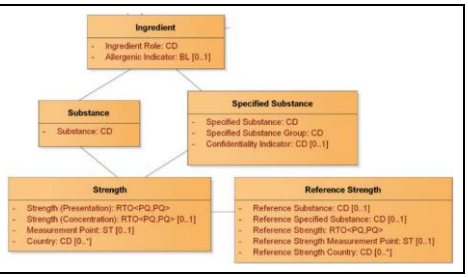
Gültig bis (BAG)	28.02.2018	

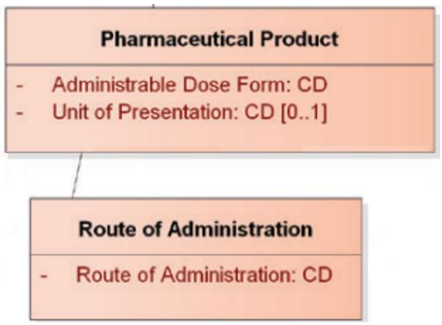
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed package	
Shelf Life Time Period	tbd		
Special Precautions of Storage	2	Im Kühlschrank (2°C – 8°C)	
	L	vor Licht Schützen	
	NF	Nicht einfrieren	
	Bei Swissmedic angefragt	Nicht schütteln	
	OVP	In der Originalverpackung aufbewahren.	

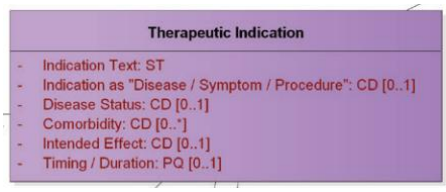
Manufactured Item			
Manufactured Dose Form	11210000	Solution for infusion	
Unit of Presentation	15060000	Vial	

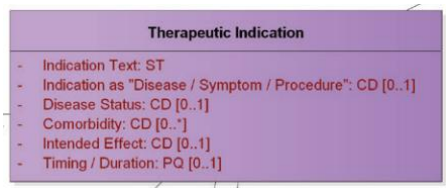
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	DPT0O3T46P	Pembrolizumabum	
Strength (presentation)	100 mg (per UoP)		

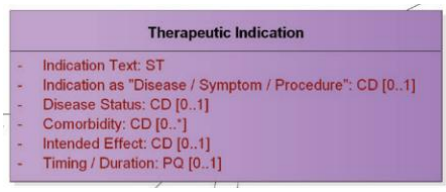
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	4QD397987E	Histidinum	
	X573657P6P	Histidini hydrochloridum monohydricum	
	6OZP39ZG8H	Polysorbatum 80	

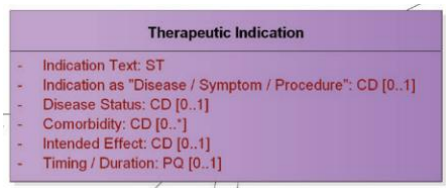
	FST467XS7D	Saccharum	
	059QF0KO0R	Aqua ad iniectabile	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11210000	Solution for infusion	
Unit of Presentation	15060000	Vial	
Route of Administration	20045000	Intravenous use	
Methode of Administration (Swissmedic)	200000002043	Infusion	

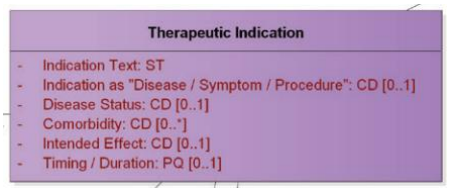
Therapeutic Indication			
Indication as	10027400	Melanom	
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10028881	Nicht-kleinzelliges Lungenkarzinom	
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10021782	Kopf- und Halskarzinom	
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10019927	Klassisches Hodgkin Lymphom	
Intended Effect	200000003194	Therapy	

Therapeutic Indication			
Indication as	10043971	Primäres mediastinales grosszelliges B-Zell-Lymphom	

Intended Effect	200000003194	Therapy	

2.5 PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk

Paxlovid, Filmtabletten	
Image	 

Quelle		
Compendium	PAXLOVID Filmtabl 4x150mg/2x100mg	compendium.ch®
SAI	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	refdata

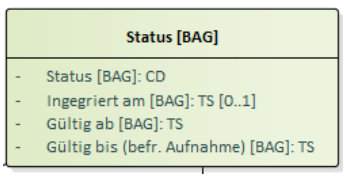
Medicinal Product			
MPID	CH-7601001010604-6879301		
Approved Dose Form (EXT)	FILM	Filmtablette	

Product Classification		
ATC (Code System)	J05AE30	
Heilmittelcode (Value)	S – Synthetika	

Medicinal Product Name			
Type (EXT)	Original		
Full Name	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk		
Invented Name Part	PAXLOVID		
Strength Part	150mg		
Strength Part	100mg		
Pharmaceutical Dose Form Part	Filmtabl		
Container or Pack Part	4x		
Container or Pack Part	2x		
Container or Pack Part	5 x 6 Stk		
Delimiter Part	/		
Country / Language			
Language	de	Deutsch	

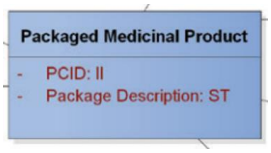
Medicinal Product Name	
Type (EXT)	BAG
Full Name	PAXLOVID Filmtabl 4x150mg/2x100mg
Invented Name Part	PAXLOVID
Strength Part	150mg
Strength Part	100mg
Pharmaceutical Dose Form Part	Filmtabl
Container or Pack Part	4x
Container or Pack Part	2x
Delimiter Part	/
Country / Language	

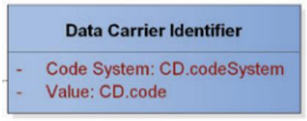
Language	de	Deutsch	

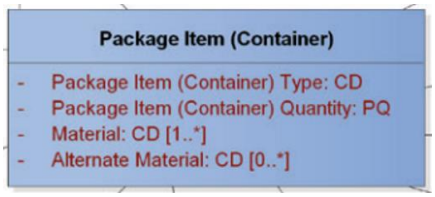
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	6879301		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	B	Befristet	
Authorisation Status Date	15.06.2022		
Validity Period End	15.06.2024		
Date of First Authorisation	15.06.2022		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	PM		
Original Generika Code (BAG)	-		
BAG Dossier-Nr. (BAG)	21529		
Status (BAG) (Medicinal Product)			
Integriert am (BAG)	01.12.2023		
gültig ab (BAG)	01.12.2023		
gültig bis (befr. Aufnahme) (BAG)	31.12.2025		

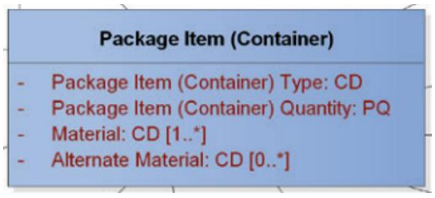
Marketing Authorisation Holder (Organisation)		
Name	Pfizer AG	
GLN	7601001010604	

Hinweis: Pack Size, eine Verpackung: 4x150mg und 2x100mg in einem Blister, 5 Blister pro Box.

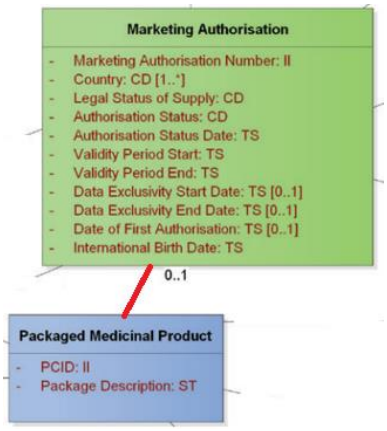
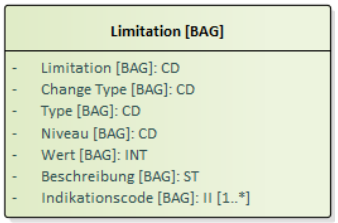
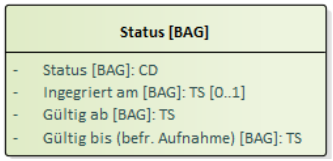
Packaged Medicinal Product		
PCID	CH-7601001010604-6879301-001	
Package Description	PAXLOVID Filmtabl 4x150mg/2x100mg 5 x 6 Stk	
Pack Size (EXT)	30 Filmtabletten	

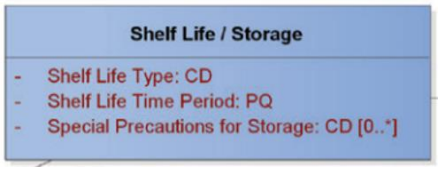
Data Carrier Identifier		
GTIN (Code System)	7680687930017	

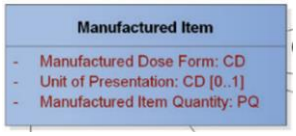
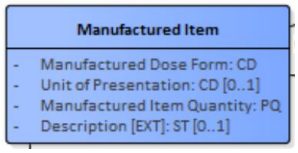
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

Packaged Item (Container)			
Package Item (Container) Type	30007000	Blister	
Package Item (Container) Quantity	1		
Material	Aluminium, Aluminium		

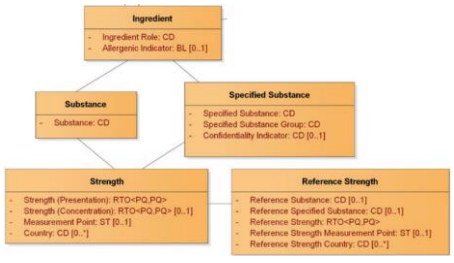
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	20	Tabletten (150 mg nirmatrelvirum) 4 Tabletten pro Blister	
Manufactured Item Quantity	10	Tabletten (100 mg ritonavirum) 2 Tabletten pro Blister	

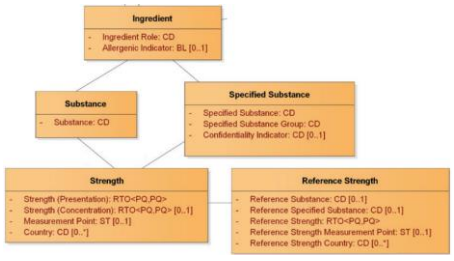
Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	68793001		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	B	Befristet	
Authorisation Status Date	15.06.2022		
Preis (BAG) (Packaged Medicinal Product)			
FAP (BAG)	CHF 958.62		
PP (BAG)	CHF 1112.85		
Preis-änderungstyp (BAG)	Preismutation bei Erstaufnahme		
Limitation (BAG) (Packaged Medicinal Product)			
Limitation (BAG)	L		
Beschreibung (BAG)	xxx		
Status (BAG) (Packaged Medicinal Product)			
Gültig ab (BAG)	01.12.2023		
Gültig bis (BAG)	31.12.2025		

Shelf Life / Storage			
Shelf Life Type	100000073403	Closed package	
Shelf Life Time Period	tbd		
Special Precautions of Storage	OVP	Im Originalkarton aufbewahren	
	NO25	Nicht über 25 °C	
	2	Im Kühlschrank (2°C - 8°C)	
	NF	Nicht einfrieren	

Manufactured Item			
Manufactured Dose Form	10221000	Filmtablette	
Unit of Presentation	15054000	Tablette	
Description (EXT)	Komponente A: Rosafarbene, ovale Filmtablette		
Description (EXT)	Komponente B: Weisse kapselförmige Tablette		

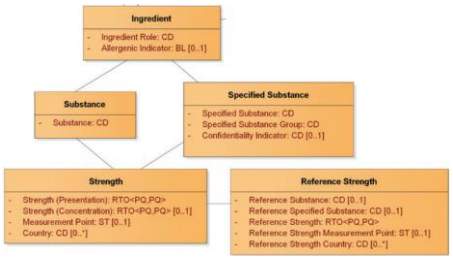
Komponente A

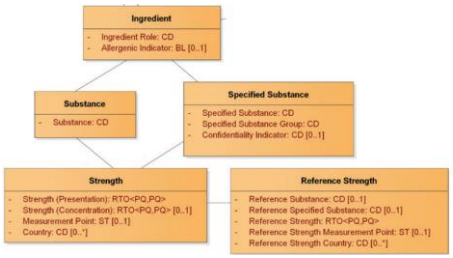
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	7R9A5P7H32	Nirmatrelvir	
Strength (presentation)	150 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	OP1R32D61U	Cellulosum microcristallinum	
	EWQ57Q8I5X	185 mg lactosum monohydricum	
	M28OL1HH48	Carmellosum natricum conexum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	7CV7WJK4UI	Natrii stearylis fumaras	

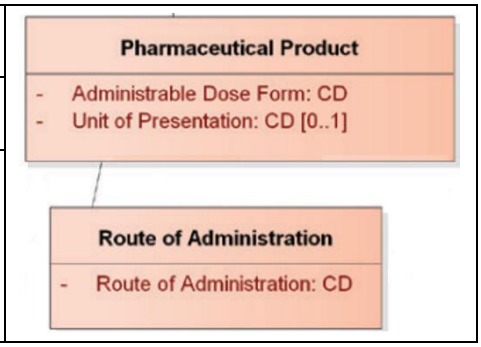
	3NXW29V3WO	Hypromellosum	
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171	
	B697894SGQ	Macrogolum 400	
	1K09F3G675	Red Iron Oxide Dehydrate E 172	
	9NEZ333N27	0.99 mg Natrium	

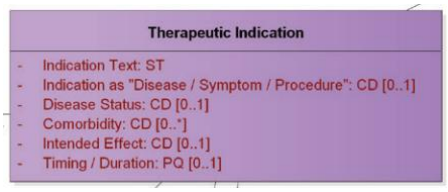
Komponente B

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	O3J8G9O825	Ritonavirum	
Strength (presentation)	150 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	9E63551N1O	Copovidonum	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	6W9PS8B71J	Sorbitani lauras	
	L11K75P92J	Calcii hydrogenophosphas	
	7CV7WJK4UI	Natrii stearylis fumaras	
	3NXW29V3WO	Hypromellosum	
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171	
	B697894SGQ	Macrogolum 400	
	YIN83H0ESV	Macrogolum 3350	
	9XZ8H6N6OH	Hydroxypropylcellulosum	
	7SEV7J4R1U	Talc	
	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	6OZP39ZG8H	Polysorbatum 80	
	9NEZ333N27	0.388 mg Natrium	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10221000	Film-coated tablet	

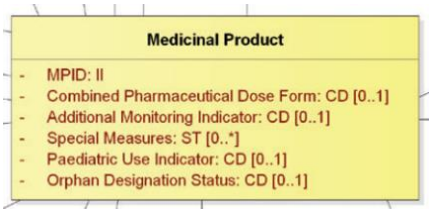
Unit of Presentation	15054000	Tablette	
Route of Administration	20053000	Oral use	
Methode of Administration (Swissmedic)	200000002052	Swallowing	

Therapeutic Indication			
Indication as	10084529	Coronavirus-Krankheit 2019 (COVID-19)	
Intended Effect	200000003194	Therapy	

2.6 TRIOGEN Kaps 250 mg Ds 100 Stk

Triogen, Kapseln	
Image	

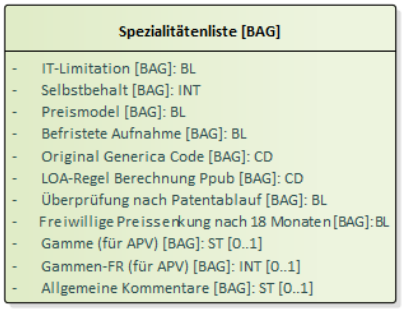
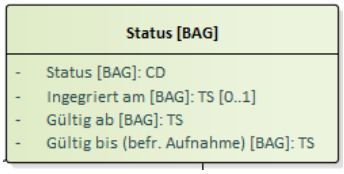
Quelle		
Compendium	TRIOGEN Kaps 250 mg	compendium.ch®
SAI	TRIOGEN Kaps 250 mg Ds 100 Stk	refdata

Medicinal Product			
MPID	CH-7601001403062-6743101		
Approved Dose Form (EXT)	KAPS	Kapsel	

Product Classification		
ATC	A16AX12	
Heilmittelcode	S – Synthetika	

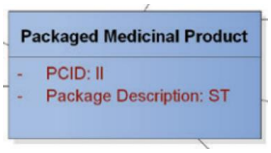
Medicinal Product Name			
Type (EXT)	Original		
Full Name	TRIOGEN Kaps 250 mg Ds 100 Stk		
Invented Name Part	TRIOGEN		
Pharmaceutical Dose Form Part	Kaps		
Strength Part	250 mg		
Container or Pack Part	Ds 100 Stk		
Country / Language			
Language	de	Deutsch	

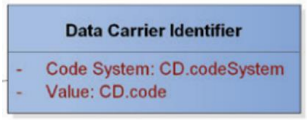
Medicinal Product Name			
Type (EXT)	BAG		
Full Name	TRIOGEN Kaps 250 mg		
Invented Name Part	TRIOGEN		
Pharmaceutical Dose Form Part	Kaps		
Strength Part	250 mg		
Country / Language			
Language	de	Deutsch	

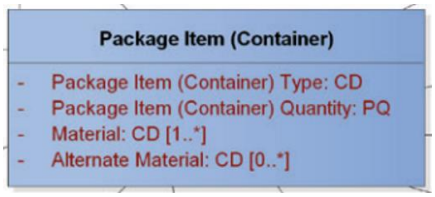
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	6743101		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	28.05.2020		
Validity Period End	27.05.2025		
Date of First Authorisation	28.05.2020		
Spezialitätenliste (BAG) (Medicinal Product)			
Selbstbehalt (BAG)	-		
Preismodell (BAG)	-		
Original Generika Code (BAG)	-		
BAG Dossier-Nr. (BAG)	21070		
Status (BAG) (Medicinal Product)			
Integriert am (BAG)	01.09.2020		
gültig ab (BAG)	01.09.2020		
gültig bis (befr. Aufnahme) (BAG)	31.12.9999		

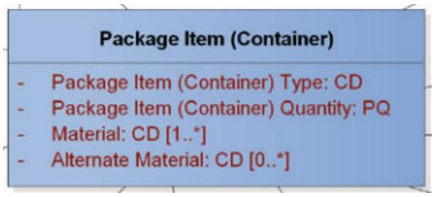
Marketing Authorisation Holder (Organisation)		
Name	IDEOGEN AG	
GLN	7601001403062	

Hinweis: Pack Size, 100 Kapseln

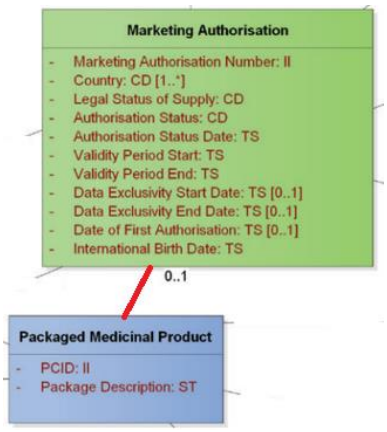
Packaged Medicinal Product		
PCID	CH-7601001403062-6743101-001	
Package Description	TRIOGEN Kaps 250 mg Ds 100 Stk	
Pack Size (EXT)	100 Kapseln(n)	

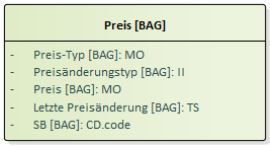
Data Carrier Identifier		
GTIN (Code System)	7680674310013	

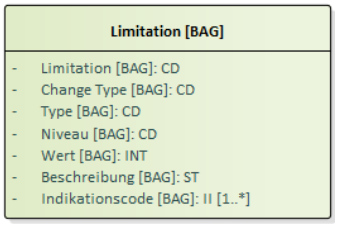
Packaged Item (Container)			
Package Item (Container) Type	30009000	Box	
Package Item (Container) Quantity	1		
Material	Karton		

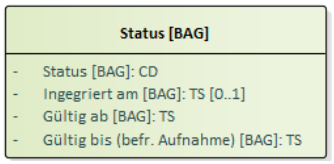
Packaged Item (Container)			
Package Item (Container) Type	30008000	Bottle	
Package Item (Container) Quantity	1		
Material	unknown		

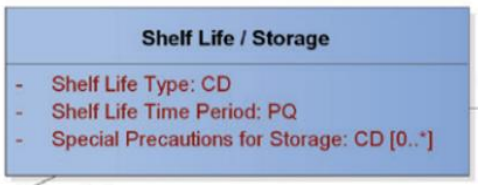
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	100	Kapseln (per box)	

Marketing Authorisation (Packaged Medicinal Product)			
Marketing Authorisation Number	67431001		
Legal Status of Supply	B	Abgabe auf ärztliche oder tierärztliche Verschreibung (B)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	28.05.2020		

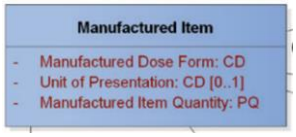
Preis (BAG) (Packaged Medicinal Product)		
FAP (BAG)	CHF 4117.12	
PP (BAG)	CHF 4466.05	
Preis-änderungstyp (BAG)	Preismutation bei Erstaufnahme	

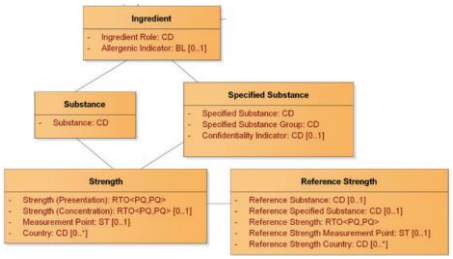
Limitation (BAG) (Packaged Medicinal Product)		
Limitation (BAG)	L	
Beschreibung (BAG)	xxx	

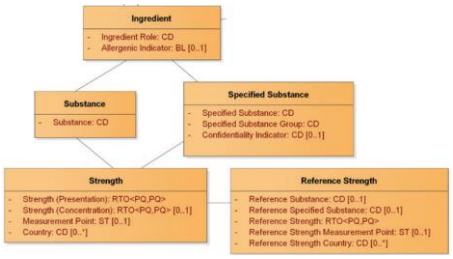
Status (BAG) (Packaged Medicinal Product)		
Gültig ab (BAG)	01.09.2020	
Gültig bis (BAG)	31.12.9999	

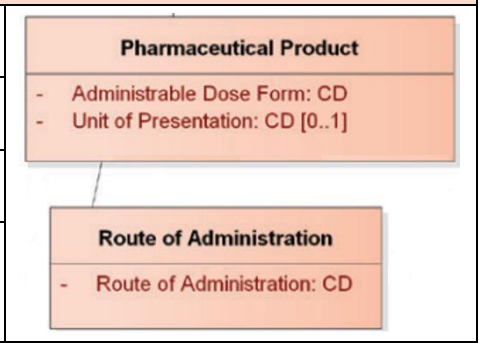
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed Package	
Shelf Life Time Period	tbd		
Special Precautions of Storage	NO30	Nicht über 30°C lagern	
	F	vor Feuchtigkeit schützen	

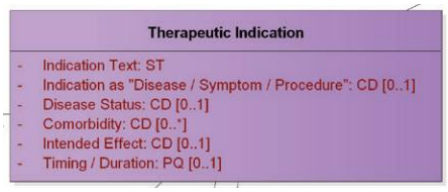
	CLOS	Den Behälter fest verschlossen halten	

Manufactured Item			
Manufactured Dose Form	10210000	Capsule, hard	

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance		Trientini dihydrochloridum	
Strength (presentation)	250 mg (per UoP)		

Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	ETJ7Z6XBU4	Silica colloidalis anhydrica	
	4ELV7Z65AP	Acidum stearicum	
	2G86QN327L	Gelatina	
	059QF0KO0R	Aqua purificata	
	368GB5141J	Natrii laurilsulfas	
	9NEZ333N27	0.0048 mg natrium	
	EX438O2MRT	YELLOW LAKE CLF 3076 (E104 AND E172) E 172 (flavum)	
	1K09F3G675	RED IRON OXIDE DEHYDRATE (E172) E 172 (rubum)	
	15FIX9V2JP	TITANII DIOXIDUM CL 77891 E 171	
	J601Y25Y5H	Lacca	
	3N8O9D1K5W	Alcohol butylicus	
	6DC9Q167V3	Propylenglycolum	
	1K09F3G675	BLACK IRON OXIDE - SYNTHETIC (E172) E 172 (nigrum)	
	WZH3C48M4T	Kalii hydroxidum	

Pharmaceutical Product / Route of Administration			
Administrable Dose Form	10210000	Capsule, hard	
Unit of Presentation	15012000	Capsule	
Route of Administration	20053000	Oral use	
Methode of Administration (Swissmedic)	200000002052	Swallowing	

Therapeutic Indication			
Indication as	100000019583	Copper metabolism disorder (Morbus Wilson)	
Intended Effect	200000003194	Therapy	

3 Abkürzungsverzeichnis

CD ..... *Concept Descriptor (Werteliste)*

EMA ..... *European Medicines Agency*

EU ..... *Europäische Union*

FHIR ..... Fast Healthcare Interoperability Resources

GSRS ..... *Global Substance Registration System*

I/O ..... Input / Output

IDMP ..... *Identification of Medicinal Product*

II ..... *Instance Identifier (Identifikationsnummer)*

JSON ..... *JavaScript Object Notation*

MPID ..... *Medicinal Product Identifier*

NCATS ..... *National Center for Advancing Translational Sciences*

SPOR ..... *Substances, Products, Organisations, Referencials*

ST ..... *String*

TS ..... *Time Stamp (Datumsangabe)*

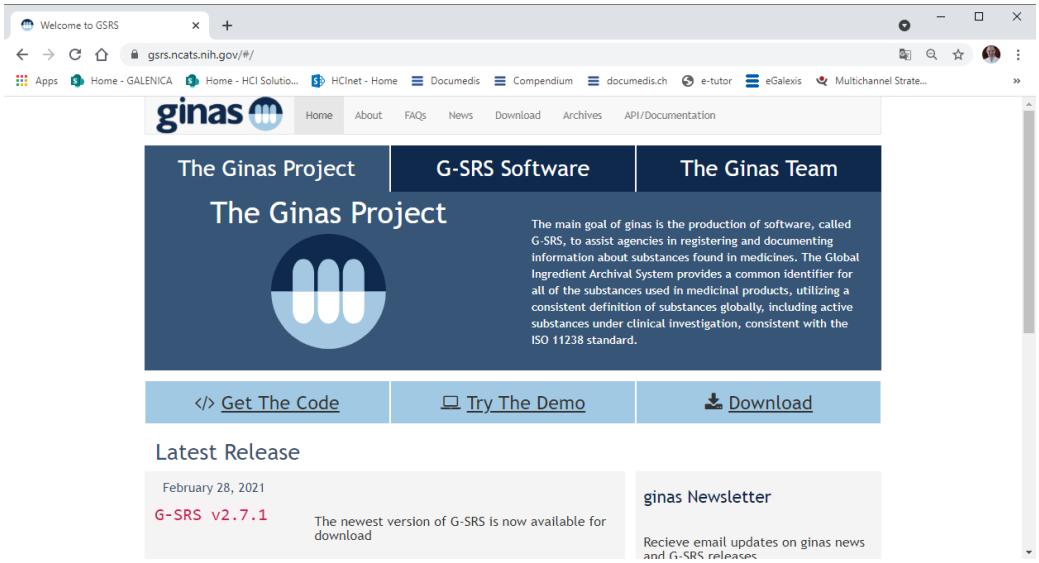
UNII ..... *Unique Ingredient Identifier*

XML ..... Extensible Markup Language

4 Websites

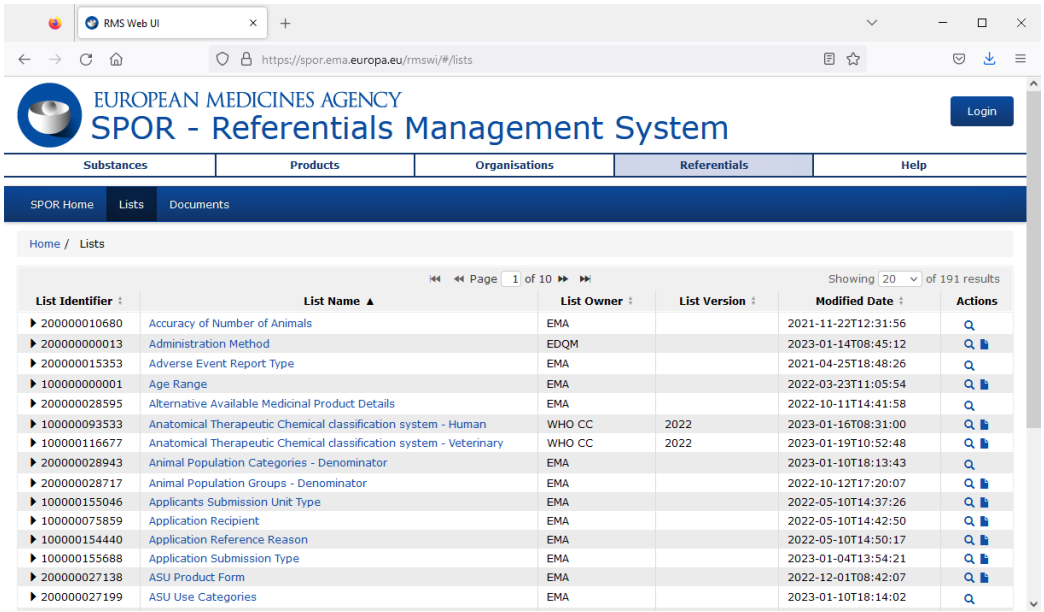
4.1.1 GSRS

https://gsrs.ncats.nih.gov/ ist die Globale Substanz-Registrierungs-Datenbank welche vom NCATS des US National Institute of Health betrieben wird.



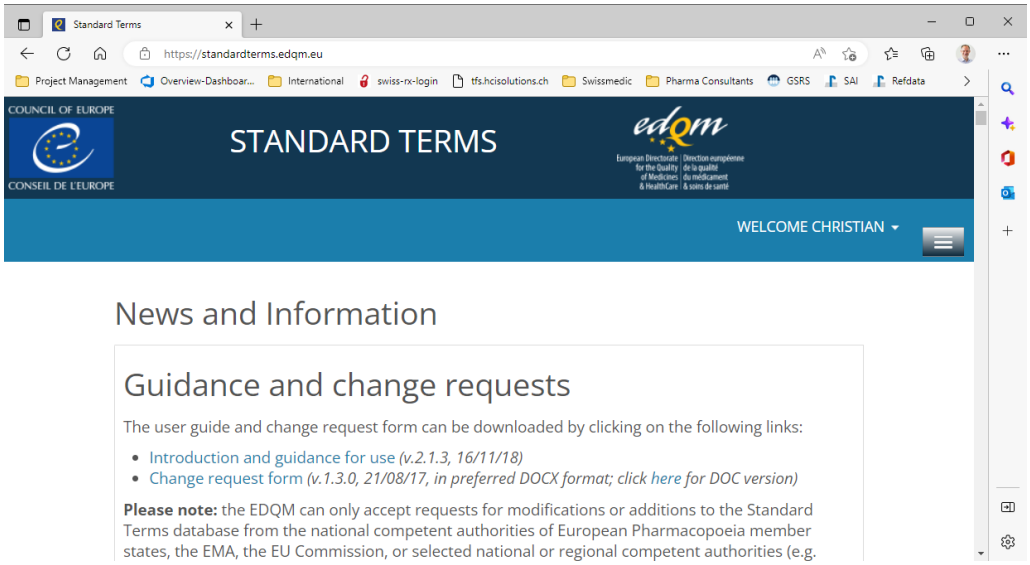
4.1.2 EMA RMS

https://spor.ema.europa.eu/rmswi/#/ ist die Website der EMA mit der Auflistung all ihrer Wertelisten.



4.1.3 EDQM Standardterms

https://standardterms.edqm.eu/ ist die Website des EDQM mit der Auflistung ihrer Wertelisten.



4.2 Gesetze und Vorgaben

4.2.1 Antwort des Bundesrates vom 7.3.2022 betreffend der Einführung von IDMP in der Schweiz

Auf Anfrage der Nationalrätin Edith Graf-Litscher antwortet der Bundesrat wie folgt:

Die Einführung von ISO IDMP ist in der Schweiz vorgesehen. Ein entsprechender Vorgehensplan für die schrittweise Einführung ist bei Swissmedic in Erarbeitung. Die Einführung soll mit den betroffenen Kreisen abgestimmt werden. Die Arzneimittelsicherheit und Patientensicherheit sind während der schrittweisen Einführung jederzeit gewährleistet. Um mit der Europäischen Arzneimittelagentur und anderen Behörden bei relevanten Arzneimitteldaten kompatibel zu sein, wurden gewisse Massnahmen bereits umgesetzt. Ob Ausnahmen für Tierarzneimittel oder Komplementär- und Phytoarzneimittel denkbar sind, ist Bestandteil der gegenwärtigen Abklärungen. Zum aktuellen Zeitpunkt geht der Bundesrat davon aus, dass weder eine Anpassung des Heilmittelgesetzes noch der entsprechenden Verordnungen nötig sein wird.

Link zum vollständigen Artikel:

https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20227054

4.2.2 Commission Implementing Regulation (EU) No 520/2012

Beiliegend die gesetzlichen Bestimmungen der Europäischen Union zur Einführung von IDMP in der EEA.

Article 25 of Commission Implementing Regulation (EU) No 520/2012 (terminology)

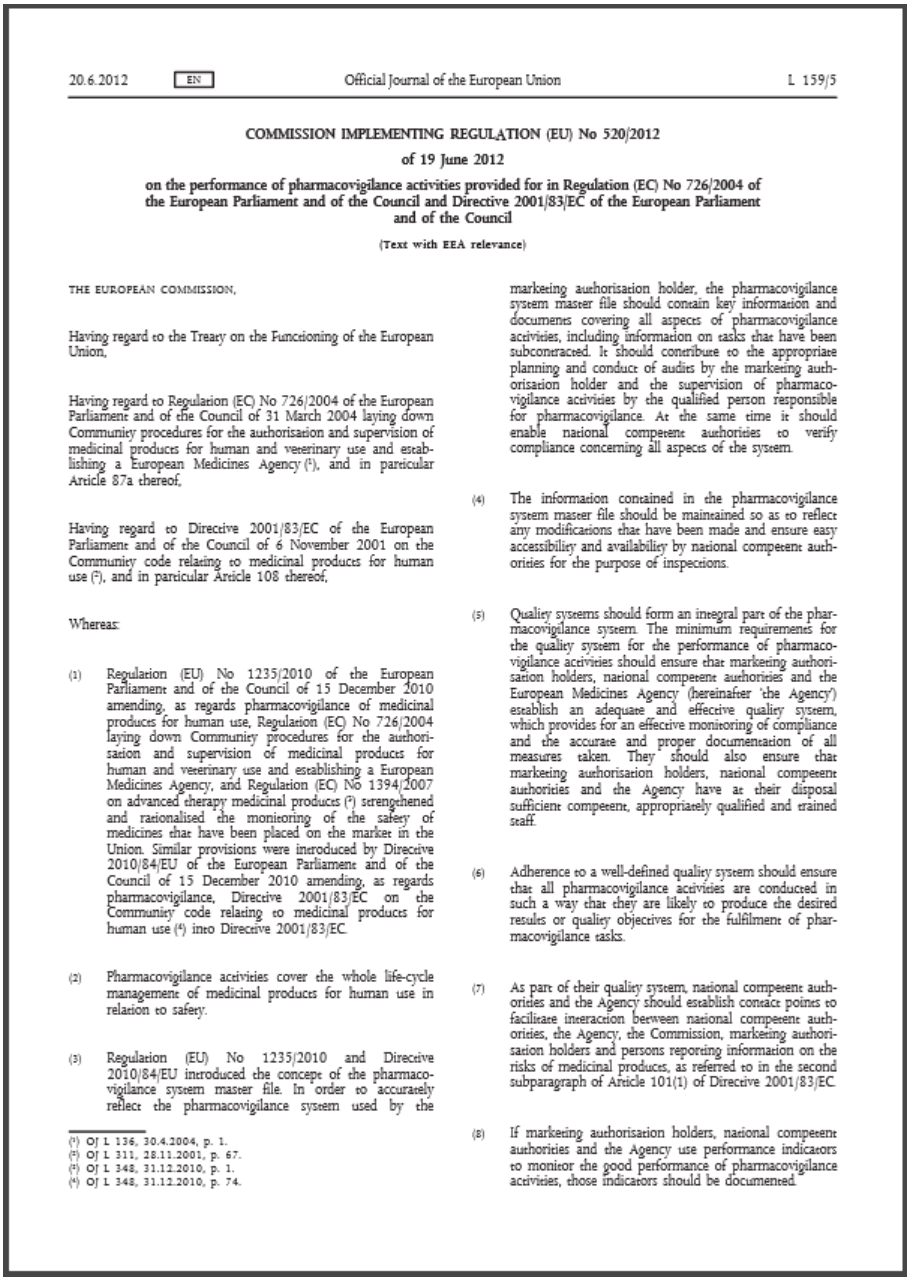
> MedDRA, Standard Terms published by European Pharmacopeia Commission and terminology set out in **EN ISO 11615, 11616, 11238, 11239 and 11240 must be used** for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of **pharmacovigilance and medicinal product information** by Member States, marketing authorisation holders and the Agency.

Article 26 of Commission Implementing Regulation (EU) No 520/2012 (formats and standards)

> **XEVMPD**, EN ISO 27953-2:2011 ICSR as well as formats and standards set out in **EN ISO 11615, 11616, 11238, 11239 and 11240** must be used for the description, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information by national competent authorities, marketing authorisation holders and the Agency.

Article 40 of Commission Implementing Regulation (EU) No 520/2012 (due date)

> The obligation on the part of marketing authorisation holders, national competent authorities and the Agency to use the terminology provided for in Art 25 and Art 26(2)shall apply from **1 July 2016**



20.6.2012 EN Official Journal of the European Union L 159/5

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012

of 19 June 2012

on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (1), and in particular Article 87a thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (2), and in particular Article 108 thereof,

Whereas:

(1) Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (3) strengthened and rationalised the monitoring of the safety of medicines that have been placed on the market in the Union. Similar provisions were introduced by Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (4) into Directive 2001/83/EC.

(2) Pharmacovigilance activities cover the whole life-cycle management of medicinal products for human use in relation to safety.

(3) Regulation (EU) No 1235/2010 and Directive 2010/84/EU introduced the concept of the pharmacovigilance system master file. In order to accurately reflect the pharmacovigilance system used by the marketing authorisation holder, the pharmacovigilance system master file should contain key information and documents covering all aspects of pharmacovigilance activities, including information on tasks that have been subcontracted. It should contribute to the appropriate planning and conduct of audits by the marketing authorisation holder and the supervision of pharmacovigilance activities by the qualified person responsible for pharmacovigilance. At the same time it should enable national competent authorities to verify compliance concerning all aspects of the system.

(4) The information contained in the pharmacovigilance system master file should be maintained so as to reflect any modifications that have been made and ensure easy accessibility and availability by national competent authorities for the purpose of inspections.

(5) Quality systems should form an integral part of the pharmacovigilance system. The minimum requirements for the quality system for the performance of pharmacovigilance activities should ensure that marketing authorisation holders, national competent authorities and the European Medicines Agency (hereinafter 'the Agency') establish an adequate and effective quality system, which provides for an effective monitoring of compliance and the accurate and proper documentation of all measures taken. They should also ensure that marketing authorisation holders, national competent authorities and the Agency have at their disposal sufficient competent, appropriately qualified and trained staff.

(6) Adherence to a well-defined quality system should ensure that all pharmacovigilance activities are conducted in such a way that they are likely to produce the desired results or quality objectives for the fulfilment of pharmacovigilance tasks.

(7) As part of their quality system, national competent authorities and the Agency should establish contact points to facilitate interaction between national competent authorities, the Agency, the Commission, marketing authorisation holders and persons reporting information on the risks of medicinal products, as referred to in the second subparagraph of Article 101(1) of Directive 2001/83/EC.

(8) If marketing authorisation holders, national competent authorities and the Agency use performance indicators to monitor the good performance of pharmacovigilance activities, those indicators should be documented.

(1) OJ L 136, 30.4.2004, p. 1.
(2) OJ L 311, 28.11.2001, p. 67.
(3) OJ L 348, 31.12.2010, p. 1.
(4) OJ L 348, 31.12.2010, p. 74.

Abbildung 1 Commission Implementing Regulation (EU) No 520/2012

Siehe: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000491.jsp

5 Versionierung

Version	Erstellt	Änderungen	Autor
1.0	12.12.2023	Initial Draft	MBK
1.1	19.12.2023	Update nach Reviews Ergänzung weiterer Produkte	CKR
1.2	10.01.2024	Ergänzung IDMP – BAG Datenmodel Erweiterungen der Daten	CKR