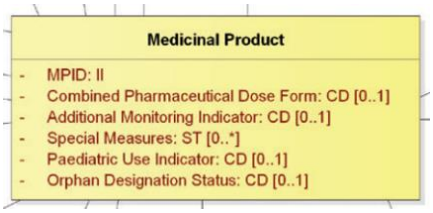
KEYTRUDA Inf Konz 100 mg/4ml Durchstf

Keytruda, Konzentrat zur Herstellung einer Infusionslösung

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

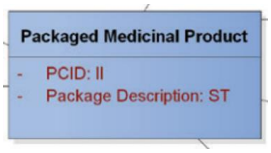
Country / Language		
Language	de	Deutsch

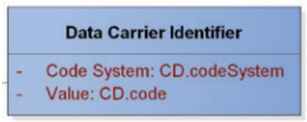
Medicinal Product Name			
Type (EXT)	BAG		
Full Name	KEYTRUDA Inf Konz 100 mg/4ml		
Invented Name Part	KEYTRUDA		
Strength Part	100 mg/4ml		
Pharmaceutical Dose Form Part	Inf Konz		
Country / Language			
Language	de	Deutsch	

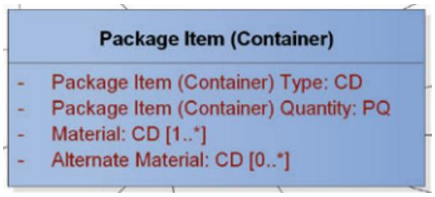
Marketing Authorisation (Medicinal Product)			
Marketing Authorisation Type (EXT)	tbd		
Marketing Authorisation Number	6623101		
Legal Status of Supply	A	Einmalige Abgabe auf ärztliche oder tierärztliche Verschreibung (A)	
Authorisation Status	Z	Zugelassen	
Authorisation Status Date	22.02.2017		
Validity Period End	31.12.9999		
Date of First Authorisation	22.02.2017		

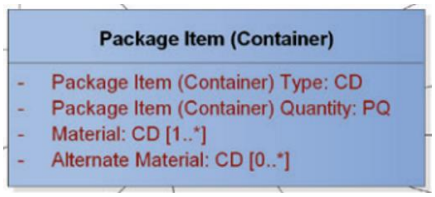
Marketing Authorisation Holder (Organisation)		
Name	MSD Merck Sharp & Dohme AG	
GLN	7601001001138	

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		

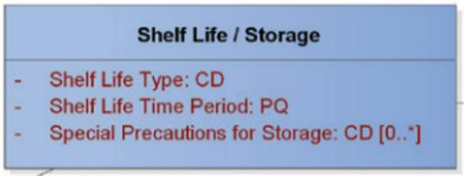
Packaged Item (Container)			
Package Item (Container) Type	30069000	Vial	
Package Item (Container) Quantity	1		
Material	Glas		

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

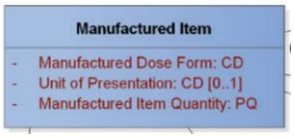
Packaged Item (Manufactured Item)			
Manufactured Item Quantity	4	ml	

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		

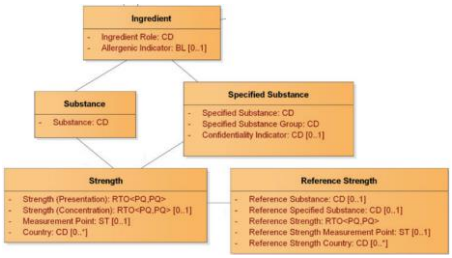
Shelf Life / Storage			
Shelf Life Type	100000073403	Closed package	
Shelf Life Time Period	tbd		
Special Precautions of Storage	2	Im Kühlschrank (2°C – 8°C)	
	L	vor Licht Schützen	
	NF	Nicht einfrieren	
	Bei Swissmedic angefragt	Nicht schütteln	
	OVP	In der Originalverpackung aufbewahren.	



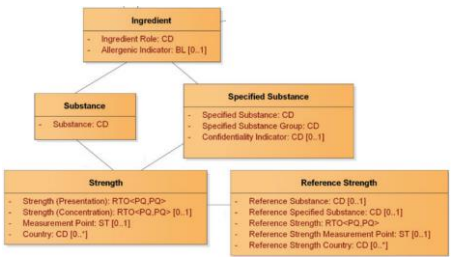
Manufactured Item			
Manufactured Dose Form	11210000	Solution for infusion	
Unit of Presentation	15060000	Vial	

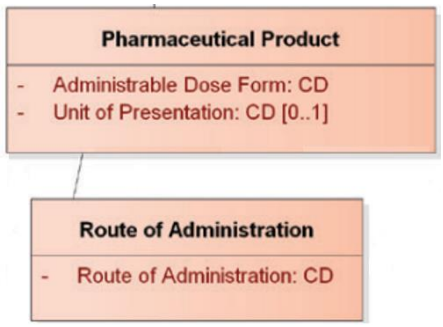


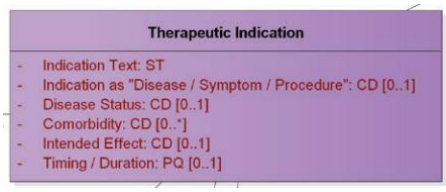
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	WIRKS	Wirkstoff	
Substance	DPT0O3T46P	Pembrolizumabum	
Strength (presentation)	100 mg (per UoP)		

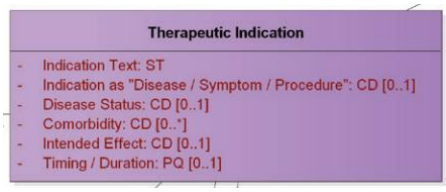


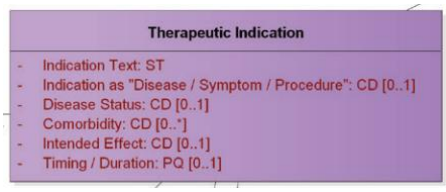
Ingredient (Manufactured Item) / Substance / Strength / Reference Strength			
Ingredient Role	HNIDK	Hilfsstoff	
Substance	4QD397987E	Histidinum	
	X573657P6P	Histidini hydrochloridum monohydricum	
	6OZP39ZG8H	Polysorbatum 80	
	FST467XS7D	Saccharum	
	059QF0KO0R	Aqua ad iniectabile	

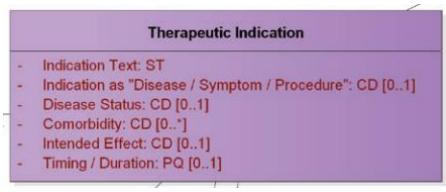


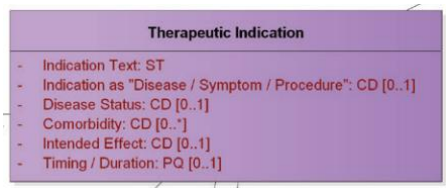
Pharmaceutical Product / Route of Administration			
Administrable Dose Form	11210000	Solution for infusion	
Unit of Presentation	15060000	Vial	
Route of Administration	20045000	Intravenous use	
Methode of Administration (Swissmedic)	200000002043	Infusion	

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	