EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database

Implementation of the requirements of Regulation (EU) 2019/6 for the Union database on veterinary medicinal products in the European Economic Area

Chapter 6: Examples for submission of legacy data

Version 1.2

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Changes made compared to the previous version:

1. Guidance watermarked "OBSOLETE".

Scope of this guidance

This document provides detailed examples on the data elements to be provided for the submission of legacy medicinal products authorised for veterinary use to the UPD.

For the purpose of this chapter, *legacy data* is defined as any data on a veterinary medicinal product authorised in a Member State with a marketing authorisation or registration valid on 28 January 2022.

The full list of data elements applicable for the legacy data submission are outlined in Chapter 4 of the Vet EU IG. The following aspects, as outlined in the Vet EU IG Chapter 2, apply also to the legacy data submission:

- The scope of the veterinary medicinal products to be provided in accordance with the provisions laid down in Articles 55 and 102 of Regulation (EU) 2019/6;
- The defining characteristics of a veterinary medicinal product that enable the unique identification of a product record by assigning the UPD product ID (level 1), the UPD permanent ID (level 2) and package ID (level 3);
Technical Specification;
- The confidentiality arrangements conforming to Article 56 of Regulation (EU) 2019/6;
- The information model for veterinary medicinal products into the UPD, which is based on the SPOR API Technical specification and HL7 FHIR specification, and also described in Chapter 5 on the
- The format, business guidance and conventions outlined in Chapter 2 of the Vet EU IG on the data elements that fall under the scope of legacy data submission into the UPD.

The following information should be considered when reading the examples table:

- Fields marked in **bold** refer to data elements classes;
- The column on European/National specify whether the data has been provided into the UPD by the Reference Member State (RMS) i.e. European or by either the RMS or the Concerned Member States (CMS) for the applicable national marketing authorisation i.e. National.
- For products approved under MRP/DCP/SRP procedures, the information will be provided following a two-step approach. First, the RMS will provide the European dataset, then the CMS will provide the national dataset.
- The conformance outlines whether the data is mandatory, conditional or optional.
- Data elements that do not apply to the relevant examples or have been already provided by other Member States in previous submission are greyed out and, when applicable, value is left blank.
- The "value code" column shows the expected content of a product submission in the FHIR message. The "value" column indicates what the value code represents or which information would be chosen/added in the web user interface. Please note that all the identifiers that are automatically assigned by the system, and in this document are for illustration only.

1. Mutual Recognition Procedure: Drontal

SPC Section 1 (Name of the veterinary medicinal product): Drontal 230/20 mg Film-coated Tablet for Cats

SPC Section 2 (Quantitative and Qualitative composition): One film-coated tablet contains Pyrantel embonate 230 mg (80 mg pyrantel base); Praziquantel 20 mg.

SPC Section 6.5 Nature and composition of immediate packaging: *2 blisters of 8 tablets; 2 blisters of 20 tablets*

Reference Member State: *Germany*

Concerned Member State: *France, Spain*

1.1. Drontal submission by the RMS

The following illustrates the data elements that the Reference Member State shall provide for the European data set and the National data set pertaining his territory.

Please note for purpose of illustration of the data, the information is to be provided following a two-step approach. The RMS must first provide the European dataset, and then the RMS will provide the national dataset.

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		77a2ed95-5695-4bbc-81d5-6f66bdbf403a	*System generated*
1.4	Permanent identifier (UUID) - MPE	National		*601232356524*	*System generated for RMS product*
1.5	(Authorised) pharmaceutical form	European	Film-coated Tablet	100000073665	
1.6	Legal status of supply (1)	National	Veterinary medicinal product subject to veterinary prescription	200000017698	
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Full application - New active substance (Art.12(3) Dir 2001/82/EC)	100000116059	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.7.2	ATC vet code(s)	European	QP52AA51	100000122207	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1)**	**European & National**			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Film-coated Tablet for Cats		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	100[illegible]0000390	
1.8.3.2	Language	European	English	100000072[illegible]47	
1.8	**Veterinary medicinal product name (2) - DE**	**European**			
1.8.1	Veterinary medicinal product name	European	Drontal 2[illegible]/20 [illegible] für Katz[illegible]		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**Eu[illegible]pean**			
1.8.3.1	Country	E[illegible]	Germany	100000000403	
1.8.3.2	Language	[illegible]	German	100000072178	
1.10	**Ph[illegible]ovigi[illegible]ice Con[illegible]ct (QPPV)**	**E[illegible]opean**			
1.10.1	QPPV Name	European	Sandra Smith	Sandra Smith	This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC-100019643	This is not a real value as the content of the field is confidential in the UPD access policy

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European		*1234501*	*System generated*
1.11.2	(Attached document) status	European	Current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document	Physical document	
1.11.8	(Attached document) title	European	eu-spc-DE-V-0101-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*601232356524 603235612987*	*Using system generated IDs for RMS & CMS products*
1.11	**Attached Document (2) - DE**	**National**			
1.11.1	(Attached document) identifier	National		*4567*	*System generated*
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	Germany	100000000403	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	German	100000072178	
1.11.7	(Attached document) content	National	Physical document	Physical document	
1.11.8	(Attached document) title	National	de-DE-V-0101-001-de.pdf		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.11.9	(Attached document) related veterinary medicinal products	National	PEI00001	*601232356524*	Using system generated ID for RMS product
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing Business Operation**	**European**			
1.13.1	Manufacturer	European		LOC-100020455	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation/ registration/entitlement information**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	DE-23456	DE-23456	
2.3	Country	National	Germany	100000000403	
2.4	Responsible authority (organisation)	National	PEI	LOC-100000023	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	22/02/2013	22/02/2013	
2.8	Product Owner (organisation)	National	Vetoquinol	LOC-100051781	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Germany	100000000403	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
2.12	Concerned member state (1)	European	France	100000000395	
2.12	Concerned member state (2)	European	Spain	100000000529	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	DE/V/0101/001	DE/V/0101/001	
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
3	**Pharmaceutical Product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration	European	Oral use	100000073619	
3.3	Target species	European	Cats	100000109056	
3.4	**Withdrawal period**	**European**			
3.4.3	Note	European			
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredient (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Pyrantel embonate	100000089059	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg / Tablet	100000110655/ 200000002152	
4.3.2.1.1	Strength (presentation single value)	European	230/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European	Pyrantel	100000080865	
4.3.3.1.1	Reference strength (presentation)	European	Mg/Tablet	100000110655/ 200000002152	
4.3.3.1.2	Reference strength (Presentation single value)	European	80		
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Praziquantel	100000147274	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/Tablet	100000110655/ 200000002152	
4.3.2.1.1	Strength (presentation single value)	European	20/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
5	**Packaged medicinal product (1)**	**European**			
5.1	Package description (1.1) -EU	European	2 blisters of 8 tablets		
5.1.1	Language (1.1) - EU	European	English	100000072147	
5.1	Package description (1.2) -DE	National	2 blister mit 8 tabletten		
5.1.1	Language (1.2) - DE	National	German	100000072178	
5.2	Pack Size (structured values)	European	16 <tablet>	16 <200000002[illegible]9>	
5.3	Package identifier	European		*PC[illegible]45632*	*[illegible]tem generated*
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	E[illegible]opean	T[illegible]	200000002109	
5.6.2	Manufactured item quantity	Eu[illegible]an	8 <Tablet>	8 <100000073664>	
5.6.3	Manufact[illegible]d dose form	Eur[illegible]ean	Tablet	100000073664	
5.7.	**Av[illegible]ity tatus**	**N[illegible]ional**			
5.7.1	[illegible]ountry	National	Germany	100000000403	
5.7.2	A[illegible]ilability statu	National	Not marketed	100000072074	
5.7.3	Availability status date	National	11/09/2021	11/09/2021	
5	**Packaged medicinal product (2)**	**European**			
5.1	Package description (2.1) -EU	European	2 blisters of 20 tablets	2 blisters of 20 tablets	
5.1.1	Language (2.1) - EU	European	English	100000072147	
5.1	Package description (2.2) -DE	National	2 blister mit 20 tabletten	2 blister mit 20 tabletten	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
5.1.1	Language (2.2) - DE	National	German	100000072178	
5.2	Pack Size (structured values)	European	40 <tablet>	40 <200000002109>	
5.3	Package identifier	European	PCKID-45633	*PCKID-45633*	*System generated*
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Tablet	2[illegible]000002109	
5.6.2	Manufactured item quantity	European	20 <tablet>	20 <1[illegible]00007366 4[illegible]>	
5.6.3	Manufactured dose form	European	Tablet	[illegible]00000073664	
5.7.2	Availability status - DE	National	Not ma[illegible]eted	100000072074	
5.7.3	Availability status date - DE	National	11/09/20[illegible]1	11/09/2021	

1.2. Drontal submission by the CMS

France, as CMS, subm[illegible]s the [illegible]ational data set for Drontal 230/20 mg Film-coated Tablet for Cats in UPD providing the follow[illegible] data:

Vet EU IG Ref.	UPD data [illegible]lement na[illegible]e	European/ National	Value	Value Code	Note
1	**V[illegible]terinary me[illegible] product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		77a2ed95-5695-4bbc-81d5-6f66bdbf403a	
1.4	Permanent identifier (2) - FR	National		*603235612987*	System generated for CMS

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.5	(Authorised) pharmaceutical form	European	Film-coated Tablet	100000073665	
1.6	Legal status of supply (1) - DE	National	Veterinary Medicinal product subject to prescription	200000017698	
1.6	Legal status of supply (2) - FR	National	Veterinary Medicinal product subject to prescription	200000017698	
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Full application - New active substance (Art.12(3) Dir 2001/82/EC)	100000116[illegible]59	
1.7.2	ATC vet code(s)	European	QP52AA51	10000012222[illegible]	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1)**	**European**			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Film-coated Tablet for Cats		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
1.8	**Veterinary medicinal product name (2)**	**European**			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Filmtablette für Katzen		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	Germany	100000000403	
1.8.3.2	Language	European	German	100000072178	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.8	**Veterinary medicinal product name (3) - FR**	**European**			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg, comprimé pelliculé pour chats	Drontal 230/20 mg, comprimé pelliculé pour chats	
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	France	1000000001[illegible]5	
1.8.3.2	Language	European	French	1000[illegible]0072175	
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	Sandra Smith		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilanc	100000155057	
1.10.3	QPPV Location	European		LOC-100019643	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European		1234501	System generated
1.11.2	(Attached document) status	European	Current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc-DE-V-0101-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		601232356524 603235612987	Using system generated IDs for RMS & CMS product
1.11	**Attached Document (2) - DE**	**National**			**Document not seen by CMS in their product**
1.11.1	(Attached document) identifier	National		4567	System generated
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	Germany	100000000403	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	German	100000072178	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	de-DE-V-0101-001-de.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		604332366524	System generated for RMS product
1.11	**Attached Document (3) - FR**	**National**			
1.11.1	(Attached document) identifier	National	8910	*8910*	*System generated*
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	France	100000000395	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	French	100000072175	
1.11.7	(Attached document) content	National	Physical document	Physical document	
1.11.8	(Attached document) title	National	fr-spc-DE-V-0101-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*603235612987*	*Using system generated ID for MS product*
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing Business Operation**	**European**			
1.13.1	Manufacturer	European		LOC-100020435	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation/registration/entitlement information (1) - DE**	**European & National**			
2.1	Authorisation/registration/entitlement	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	DE-23456		
2.3	Country	National	Germany	100000000403	
2.4	Responsible authority (organisation)	National		LOC-100000023	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	22/02/2013		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
2.8	Product Owner (organisation)	National	Vetoquinol	LOC-100051781	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Germany	100000000403	
2.12	Concerned member state (1)	European	France	10000000032	
2.12	Concerned member state (2)	European	Spain	10000000324	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	DE/V/0101/001		
2.13.2	Procedure type	European	Mutual Recognition	200000155061	
2	**Authorisation /registration/ entitlement information (2) - FR**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/0272772 1/1996	FR/V/0272772 1/1996	
2.3	Country	National	France	100000000395	
2.4	Responsible authority organisation	National	Anses	LOC-100045741	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	22/04/2013	22/04/2013	
2.8	Product Owner (organisation)	National	Vetoquinol	LOC-100051781	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
2.11	Reference member state	European	Germany	100000000403	
2.12	Concerned member state (1)	European	France	100000000322	
2.12	Concerned member state (2)	European	Spain	100000000324	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	DE/V/0101/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155[illegible]61	
3	**Pharmaceutical Product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration	European	Oral use	[illegible]00000073619	
3.3	Target species	European	Cats	100000109056	
3.4	**Withdrawal period**	**Euro[illegible]an**			
3.4.3	Note	E[illegible]ropean			
3.5	Administrab[illegible] dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**In[illegible]t (1)**	**E[illegible]opean**			
4.1	[illegible]gredient [illegible]e	European	Active	100000072072	
4.3	**[illegible]bstance**	**European**			
4.3.1	Su[illegible]ance	European	Pyrantel embonate	100000089059	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/ Tablet	100000110655/ 200000002152	
4.3.2.1.1	Strength (presentation single value)	European	230/1		
4.3.2.2	Strength (concentration)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European	Pyrantel	100000080865	
4.3.3.1.1	Reference strength (presentation)	European	Mg/ Tablet	100000110655/ 200000002152	
4.3.3.1.2	Reference strength (Presentation single value)	European	80		
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Praziquantel	100000147274	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/ Tablet	100000110655/ 200000002152	
4.3.2.1.1	Strength (presentation single value)	European	20/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product (1)**	**European**			
5.1	Package description (1.1) - EU	European	2 blisters of 8 tablets		
5.1.1	Language (1.1) - EU	European	English	100000072147	
5.1	Package description (1.2) -DE	National	2 blister mit 8 tabletten		
5.1.1	Language (1.2) - DE	National	German	100000072178	
5.1	Package description (2.3) - FR	National	2 plaquettes de 8 comprimés	2 plaquettes de 8 comprimés	
5.1.1	Language (2.3) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	16 <tablet>	16 <200000002109>	
5.3	Package identifier	European		CKID-45632	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Tablet	200000002109	
5.6.2	Manufactured item quantity	European	8 <Tablet>	8 <100000073664>	
5.6.3	Manufactured dose form	European	Tablet	100000073664	
5.7.2	Availability status (1) - DE	National	Not marketed	100000072074	
5.7.3	Availability status date (1) - DE	National	11/09/2021		
5.7.2	Availability status (2) - FR	National	Not marketed	100000072074	
5.7.3	Availability status date (2) - FR	National	11/10/2021	11/10/2021	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
5	**Packaged medicinal product (2)**	**European**			
5.1	Package description (2.1) - EU	European	2 blisters of 20 tablets		
5.1.1	Language (2.1) - EU	European	English	100000072147	
5.1	Package description (2.2) -DE	National	2 blister mit 20 tabletten		
5.1.1	Language (2.2) - DE	National	German	100000072178	
5.1	Package description (2.3) - FR	National	2 plaquettes de 20 comprimés	2 plaquette[illegible] de 20 com[illegible]imé[illegible]	
5.1.1	Language (2.3) - FR	National	French	10[illegible]0072175	
5.2	Pack Size (structured values)	European	40 <tablet>	40 <200000002[illegible]0 9>	
5.3	Package identifier	European		PCKID-45633	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	Nati[illegible]al			
5.6	**Manufactur[illegible] item**	**European**			
5.6.1	Unit of presentatio[illegible]	Eu[illegible]ean	Tablet	200000002109	
5.6.2	Ma[illegible]tured i[illegible]m quan[illegible]y	Eu[illegible]pean	20 <Tablet>	20 <10000007366 4>	
5.6.3	[illegible]anufacture[illegible] d[illegible]e form	European	Tablet	100000073664	
5.7	**Ava[illegible]ty status**	**National**			
5.7.1	Country	National	Germany	100000000403	
5.7.2	Availability status (1) - DE	National	Not marketed	100000072074	
5.7.3	Availability status date (1) - DE	National	11/09/2021		
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status (2) - FR	National	Not marketed	100000072074	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
5.7.3	Availability status date (2) - FR	National	11/10/2021	11/10/2021	

2. Boflox

SPC Section 1 (Name of the veterinary medicinal product): Boflox 100 mg/ml solution for injection for cattle and pigs

SPC Section 2 (Quantitative and Qualitative composition): Each ml contains: Active substance: Marbofloxacin 100 mg

Authorised packs: Amber glass type II vial, closed with bromobutyl rubber stoppers with aluminium tear off caps or aluminium/plastic flip-off caps.

SPC Section 6.5 Nature and composition of immediate packaging: Carton box with 1 vial of 100 ml; Carton box with 1 vial of 250 ml; Carton box with 6 vials of 100 ml; Carton box with 6 vials of 250 ml; Carton box with 10 vials of 100 ml; Carton box with 10 vials of 250 ml; Carton box with 12 vials of 100 ml; Carton box with 12 vials of 250 ml

Reference Member State: Spain

Concerned Member States: Belgium, Bulgaria, Cyprus, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovak republic, United Kingdom

This example illustrates a complex withdrawal period.

The following table illustrates how the information should be provided in the common data set by the RMS and in the national data set by CMS.

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		71a2ed95-5695-4bbc-81d5-6f66bdbf403a	System generated
1.4	Permanent identifier (1) - DE	National		*601272356524*	System generated for RMS product
1.4	Permanent identifier (2) - FR	National		*6023235652246*	System generated for CMS
1.5	(Authorised) pharmaceutical form	European	Solution for injection	100000073863	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.6	Legal status of supply	National	Veterinary Medicinal product subject to prescription	200000017698	
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Generic (abridged application) - art 13(1)	100000116061	
1.7.2	ATC vet code(s)	European	QJ01MA93	100000120579	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1)**	**European**			
1.8.1	Veterinary medicinal product name	European	Boflox 100 mg/ml solution for injection for cattle and pigs		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European		100000000390	
1.8.3.2	Language	European	English	100000072147	
1.8	**Veterinary medicinal product name (1)**	**National**			
1.8.1	Veterinary medicinal product name	National	BOFLOX 100 MG/ML SOLUTION INJECTABLE POUR BOVINS ET PORCINS		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**National**			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	Mark Smith		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC100001643	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European		1023	System Generated
1.11.2	(Attached document) status	European	current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc- ES-V-0190-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*601272356524* *602323565246*	Using system generated ID for RMS & CMS products

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.11	**Attached Document (2) - FR**	**National**			
1.11.1	(Attached document) identifier	National		1024	System Generated
1.11.2	(Attached document) status	National	Current	200000005004	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	France	100000000395	
1.11.5	(Attached document) content type	National	pdf	"applicati n/pdf"	
1.11.6	(Attached document) Language	National	French	1 00000072	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	fr-spc- -V-0190-00 .pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*602323565246*	Using system generated ID for CMS product
1.12	**Product cross-reference**	**E n & National**			
1.12.1	Product c ss-reference e	E pea & Nati nal			
1.12.2	Ref n oduct dentifier	Eu pean & ational			
1.12.3	ource prod t id ntifier	National			
1.13	**Ma uring Business Operation (1)**	**European**			
1.13.1	Manufacturer	European	INDUSTRIAL VETERINARIA-Spain	LOC-100019643	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
1.13	**Manufacturing Business Operation (2)**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.13.1	Manufacturer	European	KELA- Belgium	LOC-100019925	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
1.13	**Manufacturing Business Operation (3)**	**European**			
1.13.1	Manufacturer	European	ANIMEDICA HERSTELLUNGS- Germany	LOC-100022291	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation/ registration/entitlement information (FR)**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/5[illegible]8/2013		
2.3	Country	National	France	100000000395	
2.4	Responsible authority (organisation)	National		LOC-100045741	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	22/02/2013		
2.8	Product Owner organisation	National		LOC-100019643	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Spain	100000000529	
2.12	Concerned member state (1)	European	Belgium	100000000337	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
2.12	Concerned member state (2)	European	Bulgaria	100000000349	
2.12	Concerned member state (3)	European	Cyprus	100000000375	
2.12	Concerned member state (4)	European	Czech Republic	100000000376	
2.12	Concerned member state (5)	European	France	100000000395	
2.12	Concerned member state (6)	European	Germany	100000000403	
2.12	Concerned member state (7)	European	Greece	1000000[illegible]0406	
2.12	Concerned member state (8)	European	Ireland	1[illegible]00000004[illegible]	
2.12	Concerned member state (10)	European	Italy	10[illegible]000000430	
2.12	Concerned member state (11)	European	Hunga[illegible]	1000[illegible]0000421	
2.12	Concerned member state (12)	European	Lithua[illegible]	100000000450	
2.12	Concerned member state (13)	Eur[illegible]ean	[illegible]uxemb[illegible]urg	100000000451	
2.12	Concerned member state (14)	Eu[illegible]an	Netherlands	100000000478	
2.12	Concerned member sta[illegible] (15)	Eur[illegible]ean	Poland	100000000500	
2.12	C[illegible]ncerned [illegible]ember sta[illegible] [illegible]6)	[illegible]uropean	Portugal	100000000501	
2.12	C[illegible]ncerned me[illegible]ate (17)	European	Romania	100000000505	
2.12	Concerned member state (18)	European	Slovakia	100000000523	
2.12	Concerned member state (19)	European	United Kingdom (Northern Ireland)	240000000000	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	ES/V/0190/001		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
2.13.2	Procedure type	European	Decentralised procedure	100000155060	
3	**Pharmaceutical Product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration (1)	European	Intramuscular use	10000007360	
3.3	Target species (1)	European	Cattle	100000108893	
3.4	**Withdrawal period (1)**	**European**			
3.4.3	Note	European	Indication Respiratory Mastitis Dosage 2 mg/kg for 3 days (IV/IM/SC) 8 mg/kg on a single occasion (IM) 2 mg/kg for 3 days (IV/IM/SC) Meat and offal 6 days 3 days 6 days Milk 36 hours 72 hours 36 hours		
3.2	Route of administration (2)	European	Subcutaneous use	100000073633	
3.3	Target species (2)	European	Cattle	100000108893	
3.4	**Withdrawal period (2)**	**European**			
3.4.3	Note	European	Indication Respiratory Mastitis Dosage 2 mg/kg for 3 days (IV/IM/SC) 8 mg/kg on a single		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
			occasion (IM) 2mg/kg for 3 days (IV/IM/SC) Meat and offal 6 days 3 days 6 days Milk 36 hours 72 hours 36 hours		
3.2	Route of administration (3)	European	Intravenous use	100000073611	
3.3	Target species (3)	European	Cattle	10000010889	
3.4	**Withdrawal period (3)**	**European**			
3.4.3	Note	European	Indication Respiratory Mastitis Dosage 2 mg/kg for 3 days (IV/IM/SC) 8 mg/kg in a single ion (I 2mg/k for 3 days (IV/IM/S) Meat an offal 3 days 6 days Milk 36 hours 72 hours 36 hours		
3.2	Route of administrat n (4)	pea	Intramuscular use	100000073600	
3.3	T get sp cies)	E opean	Pig	100000109151	
3.4	**Withdrawa riod (4)**	**European**			
3.4.3	No	European	Meat and offal: 4 days		
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredient**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Marbofloxacin	100000081743	
4.3.2	**Strength (quantitative composition)**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	mg /ml	100000110655/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	100/1		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product (1)**	**European**			
5.1	Package description (1.1) - EU	European	Carton box with 1 vial of 100 ml		
5.1.1	Language (1.1) - EU	European	English	100000072147	
5.1	Package description (1.2)-FR	National	Boîte de 1 flacon de 100 ml		
5.1.1	Language (1.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	1 <vial>	1 <200000002158>	
5.3	Package identifier	European		System generated	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6	**Manufactured item (1)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	10000007207	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (2)**	**European**			
5.1	Package description (2.1) – EU	European	Carton box with 1 vial of 250 ml		
5.1.1	Language (2.1) - EU	European	Engli	10 072147	
5.1	Package description (2.2)-FR	National	Boîte de 1 flac de 25 ml		
5.1.1	Language (2.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	Eur pean	<Via	1 <200000002158>	
5.3	Package identifier	Eur pean		PCKID-30002	System generated
5.4	Legal stat of supply	Nationa			
5.5	**Ma g authorisa on package vel)**	**Nat ional**			
5.5.1	M keting auth on number (package level)	National			
5.6	**Manufactured item (2)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	250 ml	250 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (3)**	**European**			
5.1	Package description (3.1) – EU	European	Carton box with 6 vials of 100 ml		
5.1.1	Language (3.1) - EU	European	English	100000072047	
5.1	Package description (3.2)-FR	National	Boîte de 6 flacons de 100 ml		
5.1.1	Language (3.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	6 <vial>	6 <200000002158>	
5.3	Package identifier	European		PCKID-30003	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (3)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 ml	100 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (4)**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.1	Package description (4.1) – EU	European	Carton box with 6 vials of 250 ml		
5.1.1	Language (4.1) - EU	European	English	100000072147	
5.1	Package description (4.2)-FR	National	Boîte de 6 flacons de 250 ml		
5.1.1	Language (4.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	6 <vial>	6 <200000002158>	
5.3	Package identifier	European		PCKID-30004	ystem generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (4)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	Eur an	250 <m >	250 <100000110662>	
5.6.3	Manufactured dose form	E n	Solution for injection	100000073863	
5.7	**Availabi y status**	**Na onal**			
5.7.1	Coun ry	Nat nal	France	100000000395	
5.7.2	vailability tatus - FR	National	Not marketed	100000072074	
5.7.3	ailability sta s dat FR	National	30/06/2021		
5	**Packaged medicinal product (5)**	**European**			
5.1	Package description (5.1) – EU	European	Carton box with 10 vials of 100 ml		
5.1.1	Language (5.1) - EU	European	English	100000072147	
5.1	Package description (5.2)-FR	National	Boîte de 10 flacons de 100 ml		
5.1.1	Language (5.2) - FR	National	French	100000072175	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.2	Pack Size (structured values)	European	10 <vial>	10 <200000002158>	
5.3	Package identifier	European		PCKID-30005	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (5)**	**European**			
5.6.1	Unit of presentation	European	Vial	2[illegible]	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <[illegible]0000110662>	
5.6.3	Manufactured dose form	European	Solution for inject[illegible]	1[illegible]3863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	Nati[illegible]	Not mar[illegible]eted	100000072074	
5.7.3	Availability status date - FR	N[illegible]tional	30/06/2021		
5	**Packaged medicinal product [illegible])**	**European**			
5.1	Package descr[illegible]ption (6.1) - E[illegible]	Euro[illegible]ean	Carton box with 10 vials of 250 ml		
5.1.1	[illegible]anguage (6.1) - EU	European	English	100000072147	
5.1	P[illegible]ckage des[illegible]iptio[illegible] (6.2)-FR	National	Boîte de 10 flacons de 250 ml		
5.1.1	Language (6.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	10 <vial>	10 <200000002158>	
5.3	Package identifier	European		PCKID-30006	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation**	**National**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
	(package level)				
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (6)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	250 <ml>	250 <100000110662	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000393	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (7)**	**European**			
5.1	Package description (7.1) - EU	European	Carton box with 12 vials of 100 ml		
5.1.1	Language (7.1) - EU	European	English	100000072147	
5.1	Package description (7.2)-FR	National	Boîte de 12 flacons de 100 ml		
5.1.1	Language (7.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	12 <vial>	12 <200000002158>	
5.3	Package identifier	European		PCKID-30007	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (7)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.2	Manufactured item quantity	European	100 <ml>	100 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (8)**	**European**			
5.1	Package description (8.1) - EU	European	Carton box with 12 vials of 250 ml		
5.1.1	Language (8.1) - EU	European	English	100[illegible]0072147	
5.1	Package description (8.2) -FR	National	Boîte de 12 flacons de 250 ml		
5.1.1	Language (8.2) - FR	National	French	10[illegible]000072175	
5.2	Pack Size (structured values)	European	12 <vi[illegible]>	12 <200000002158>	
5.3	Package identifier	Euro[illegible]an		PCKID-30008	System generated
5.4	Legal status of supply	N[illegible]tional			
5.5	**Marketing authoris[illegible]ion (package level)**	**National**			
5.5.1	M[illegible]rketin[illegible] [illegible]uthorisatio[illegible] [illegible]umber ([illegible]ackage lev[illegible]l)	N[illegible]tional			
5.6	**Ma[illegible]ufact[illegible]ed item (8)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	250 <ml>	250 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		

3. Hipracox

SPC Section 1 (Name of the veterinary medicinal product): Hipracox Broilers Oral suspension for chicken

SPC Section 2 (Quantitative and Qualitative composition): Each 0.007 m dose of vaccine contains the following numbers of sporulated oocysts derived from five pre[illegible]tenuated lines of coccidia:

*Eimeria acervulina, strain 003..... 300 – 390 **

*Eimeria maxima, strain 013..... 200 – 260 **

*Eimeria mitis, strain 006.....300 – 390 **

*Eimeria praecox, strain 007..... 300 – 390 **

*Eimeria tenella, strain 004.....250 – 32[illegible] **

SPC Section 6.5 Nature and composition of immediate packaging: HIPRACOX BROILERS and UNIFLOCK are packed independently. Both are packed with the same sales presentation:

Cardboard box with 1 vial 10 ml with 1,000 doses.

Cardboard box with 1 vial 50 ml with 5,000 doses.

Cardboard box with 10 vials 10 ml [illegible]1,000 doses.

Cardboard box with 10 vials 5[illegible] ml of 5,0[illegible] doses.

This example illustrates [illegible]mmunological.

The following table illustrates how the information should be provided in the common data set by the RMS and in the national data set by CMS. [1]

Vet EU IG Ref.	UPD[illegible] element name	European / National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	

[1] Please note that additional packs are authorised for Hipracox, however this example illustrates how to provide the data for the listed packs only. In the real submission the remaining packs should be submitted in line with the practices shown and as described in Chapter 2 of the Vet EU IG.

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		73a2ed95-5695-4bbc-81d5-6f66bdbf403a	System generated
1.4	Permanent identifier (1) – (Spain)	National		*601232356424*	System generated for RMS
1.4	Permanent identifier (2) - France	National		*601232356534*	System generated for CMS
1.5	(Authorised) pharmaceutical form	European	Oral suspension	100000073362	
1.6	Legal status of supply	National	Veterinary Medicinal product subject to prescription	200000[illegible]698	
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Full application New active substance (Article 13(3) of Directive No 2001/82/EC)	100000116058	
1.7.2	ATC vet code(s)	European	QI01AN01	100000119506	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name**	**European**			
1.8.1	Veterinary medicinal product name	European	Hipracox Broilers Oral suspension for chicken		
1.8.2	Name Part	European & National			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	Jane Do		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC-1[illegible]4177	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European	[illegible]	[illegible]7890	System generated
1.11.2	(Attached document) status	European	current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	Pdf	"application/pdf"	
1.11.6	(Attached document) language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc- ES-V-0327-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*601232356424* *601232356534*	Using system generated IDs for RMS & CMS products
1.11	**Attached Document (2) - FR**	**National**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.11.1	(Attached document) identifier	National		127333	System generated
1.11.2	(Attached document) status	National	current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	France	100000000395	
1.11.5	(Attached document) content type	National	Pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	French	10000007[illegible]175	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	fr-spc- ES-V-0327-001-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*601232356534*	Using system generatedID for CMS
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference Product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing business operation**	**European**			
1.13.1	Manufacturer	European		LOC-100010373	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation/registration/entitlement information - FR**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing Authorisation	220000000061	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
2.2	Authorisation/registration/entitlement number	National	FR/V/2510096 9/2008		
2.3	Country	National	France	100000000395	
2.4	Responsible authority (organisation)	National	Anses	LOC-100045741	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	03/01/2008		
2.8	Product Owner (organisation)	National	LABORATORIOS HIPRA	LOC-10001417	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Spain	100 000324	
2.12	Concerned member state (1)	European	Belgium	1 0000000318	
2.12	Concerned member state (2)	European	Denmark	100000000331	
2.12	Concerned member state (3)	European	France	100000000322	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	ES/V/0327/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
3	**Pharmaceutical product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration	European	Coarse spray	100000170847	
3.3	Target species	European	Broiler	100000108934	
3.4	**Withdrawal period**	**European**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
3.4.3	Note	European	Meat and offal, 0 Days		
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredient (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Eimeria acervulina, strain 003, Live	300000008520	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	Oocyst(s)/ml	100000025199/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	390/0.00		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength presentation single value	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
4.3.1	Substance	European	Eimeria maxima, strain 013, Live	300000008559	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	Oocyst(s)/ ml	200000025199/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	260/0.007		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Eimeria mitis, strain 006, Live	300000008486	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	Oocyst(s)/ ml	200000025199/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	390/0.007		

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (4)**	**European**			
4.1	Ingredient role	European	Active	100000072172	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Eimeria [illegible] strain [illegible]07	300000008554	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	Oocyst(s)/ ml	200000025199/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	390/0.007		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength	European			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
	(concentration) - denominator				
4	**Ingredient (5)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Eimeria tenella, strain 004	300000008493	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	Oocyst(s)/ ml	200000025199/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	325/0.007		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product (1)**	**European & National**			
5.1	Package description	European	Cardboard box with 1,000 doses in a vial 10 ml, Type I colourless glass flasks with Type I polymeric elastomer closures and		

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
			aluminium Flip-caps containing a suspension of Eimeria acervulina, strain 003, Eimeria maxima, strain 013, Eimeria mitis, strain 006, Eimeria praecox, strain 007, Eimeria tenella, strain 004		
5.1.1	Language	European	English	100000072147	
5.2	Pack Size (structured values)	European	1 <vial>	<200000002158>	
5.3	Package identifier	European		PCKID- 33001	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	1000 <Dose>/ 10 <ml>	100 <200000016427>/ 10 <100000110662>	
5.6.3	Manufactured dose form	European	Oral suspension	100000073362	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/08/2021		
5	**Packaged medicinal product (2)**	**European & National**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.1	Package description	European	Cardboard box with a 5,000 doses in a vial 50 ml, Type I colourless glass flasks with Type I polymeric elastomer closures and aluminium Flip-caps containing a suspension of Eimeria acervulina, strain 003, Eimeria maxima, strain 013, Eimeria mitis, strain 006, Eimeri praecox, 007, Eimeri tenella, rain 004		
5.1.1	Language	Eur ean	English	100000072147	
5.2	Pack Size (structured values)	uropean	1 <Vial>	1 <200000002158>	
5.3	Package iden	European		PCKID- 33002	System generated
5.4	Legal stat of supply	Na ional			
5.5	**Marketi uthorisat n package le el)**	**National**			
5.5.1	M rketing aut isat n number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	5000 <Dose>/ 50 <ml>	5000 <200000016427>/ 50 <100000110662>	
5.6.3	Manufactured dose form	European	Oral suspension	100000073362	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/08/2021		
5	**Packaged medicinal product (3)**	**European**			
5.1	Package description	European	Cardboard box with 10 vials of 10 ml with 1,000 doses, Type I colourless glass flasks with Type I polymeric elastomer closures and aluminium Flip-cap containing a suspension of Eimeria acervulina, strain 004, Eimeria maxima, strain 013, Eimeria mitis, strain 006, Eimeria praecox, strain 007, Eimeria tenella, strain 004		
5.1.1	Language	European	English	100000072147	
5.2	Pack Size (strength values)	European	10 <vial>	10 <200000002158>	
5.3	Package identifier	European		PCKID- 33003	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	1000 <Dose>/ 10 <ml>	1000 <200000016427>/ 10 <100000110662>	
5.6.3	Manufactured dose form	European	Oral suspension	100000073362	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000[illegible]95	
5.7.2	Availability status - FR	National	Not marketed	100000[illegible]2074	
5.7.3	Availability status date - FR	National	30/08/2021		
5	**Packaged medicinal product (4)**	**European**			
5.1	Package description	European	Cardboard box w[illegible] 10 vials of [illegible] ml [illegible].000 doses, [illegible]ype I colourle[illegible] glass flas[illegible]s with Typ[illegible] I [illegible]lym[illegible]ic elastomer closures and aluminium Flip-caps containing a suspension of Eimeria acervulina, strain 003, Eimeria maxima, strain 013, Eimeria mitis, strain 006, Eimeria praecox, strain 007, Eimeria tenella, strain 004		
5.1.1	Language	European & National	English	100000072147	
5.2	Pack Size (structured values)	European	10 <vial>	10 <200000002158>	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.3	Package identifier	European		PCKID- 33004	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	s	Vial	2000000[illegible]2158	
5.6.2	Manufactured item quantity	European	5000 <Dose>/ 50 <ml>	500[illegible] <[illegible]000000164[illegible]7>/ [illegible]0 <10[illegible]00110662>	
5.6.3	Manufactured dose form	European	Oral suspension	[illegible]000073362	
5.7	**Availability status**	**National**			
5.7.1	Country	National	[illegible]ce	1[illegible]0000000395	
5.7.2	Availability status - FR	National	Not mar[illegible]eted	100000072074	
5.7.3	Availability status date - FR	Nati[illegible]al	30/08/2[illegible]21		

4. Multishield

SPC Section 1 (Name of the veterinary medicinal product): Multishield DC Intramammary Suspension for Cows

SPC Section 2 (Quantitative and Qualitative composition):

Neomycin 70 000 IU (corresponding to Neomycin Sulphate 100 mg)

Penethamate 77.2 mg (corresponding to Penethamate Hydriodide 100 mg)

Benzylpenicillin 227.2 mg (corresponding to Procaine Benzylpenicillin 400 mg)

SPC Section 6.5 Nature and composition of immediate packaging: Syringes packed in cartons of 24 syringes or buckets of 120 syringes.

Reference Member state: Ireland

Concerned Member States: Belgium, France, Germany.

This example illustrates a complex composition (ref strength/strength) and several active substances.

The following table illustrates how the information should be provided in the common data set by the RMS and in the national data set by CMS.

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		88a2ed95-5695-4bbc-81d5-6f66bdbf403a	System generated
1.4	Permanent identifier	National		*601232356554*	System generated for RMS
1.4	Permanent identifier	National		*609876356556*	System generated for CMS
1.5	(Authorised) pharmaceutical form	European	Intramammary suspension	100000073893	
1.6	Legal status of supply	National	Veterinary Medicinal product subject to prescription	200000017698	
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Generic application (Article 13(1) of Directive No 2001/82/EC)	100000116061	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.7.2	ATC vet code(s)	European	QJ51RC22	100000120837	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1) - EU**	**European**			
1.8.1	Veterinary medicinal product name	European	Multishield DC Intramammary Suspension for Cows		
1.8.2	Name Part	European			
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
1.8	**Veterinary medicinal product name (2) - FR**	**National**			
1.8.1	Veterinary medicinal product name	National	MULTISHIELD DC SUSPENSION INTRAMAMMAIRE POUR VACHES		
1.8.2	Name Part	National			
1.8.3	**Country/Language**	**National**			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	Adam Smith		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.10.3	QPPV Location	European		LOC-100014156	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European		10005	System generated
1.11.2	(Attached document) status	European	Current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	English	100000072147	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc-[illegible] V-0277-0[illegible]-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*601232356554 609876356556*	Using system generated IDs for RMS & CMS
1.11	**Attached Document (2) - R**	**National**			
1.11.1	(Attached document) identifier	National		10006	System generated
1.11.2	(Attached document) status	National	current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	France	100000000395	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	French	100000072175	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	fr-spc-IE-V-0277-001-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*601232356534*	System generated for CMS
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing Business Operation**	**European**			
1.13.1	Manufacturer	European		LOC-100014156	
1.13.2	Manufacturing activity	European	Manufacture responsible for batch certification	100000160407	
2	**Authorisation /registration/ entitlement information - FR**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/9473258 8/2013		
2.3	Country	National	France	100000000395	
2.4	Responsible authority (organisation)	National		LOC-100045741	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	24/01/2013		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
2.8	Product Owner (organisation)	National	BIMEDA ANIMAL HEALTH.	LOC-100014156	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Ireland	100000000427	
2.12	Concerned member state (1)	European	Belgium	100000000337	
2.12	Concerned member state (2)	European	France	10000000[illegible]95	
2.12	Concerned member state (3)	European	Germany	1[illegible]0000000403	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	IE/V/027/[illegible]		
2.13.2	Procedure type	European	Mutual Recognitio[illegible]	[illegible]00000155061	
3	**Pharmaceutical Product**	**Eur[illegible]an**			
3.1	**Ingredient**	**E[illegible]ropea**			
3.2	Route of administratio[illegible]	Eu[illegible]an	[illegible]ntramamm ary use	100000073599	
3.3	Target spe[illegible]es	E[illegible]opea	Cow	100000108888	
3.4	**Wi[illegible]val [illegible]eriod**	**Eu[illegible]opean**			
3.4.3	[illegible]ote	European	Meat and Offal: 28 days. Milk: 96 hours post calving in cows with a dry period of more than 50 days. 50 days plus 96 hours after treatment from cows with a dry period of 50 days or less.		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredient (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Neomycin sulphate	100000090029	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/ Syringe	100000110655/ 200000002150	
4.3.2.1.1	Strength (presentation single value)	European	100/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European	Neomyc	00000090456	
4.3.3.1.1	Reference strength (presentation)	Euro an	I/ syrin e	100000110671/ 200000002150	
4.3.3.1.2	Reference strength (Presentati single va)	Eu an	0 000		
4.3.3.2	Reference str th (ncentr ion)	Euro ean			
4.3.3.2.1	eference rength (ncentrati) - d min tor	European			
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Penethamate Hydriodide	100000079773	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/ Syringe	100000110655/ 200000002150	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.2.1.1	Strength (presentation single value)	European	100/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European	Penethamate	100000079753	
4.3.3.1.1	Reference strength (presentation)	European	Mg/ Syringe	100000110655/ 20000000215	
4.3.3.1.2	Reference strength (Presentation single value)	European	77,2		
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (3)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Procaine Benzylpenicillin	100000090112	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Mg/ Syringe	100000110655/ 200000002150	
4.3.2.1.1	Strength (presentation single value)	European	400/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**				

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.3.1	Reference (Active) Substance		Benzylpenicillin	100000091070	
4.3.3	**Reference Strength**				
4.3.3.1	Reference (Active) Substance		Benzylpenicillin	100000091070	
4.3.3.1.1	Reference strength (presentation)		Mg/ Syringe	100000110655/ 200000002150	
4.3.3.1.2	Reference strength (Presentation single value)		227,2		
4.3.3.2	Reference strength (concentration)				
4.3.3.2.1	Reference strength (concentration) - denominator				
5	**Packaged medicinal product (1)**	**European**			
5.1	Package description	European	Low density Polyethylene intramammary 24 syringe, containing 4.5g intramammary suspension.		
5.1.1	Language	European	English	100000072147	
5.2	Package (structure values)	European	24 <syringe>	24 <200000002150>	
5.3	Package identifier	European		PCKID-41001	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.1	Unit of presentation	European	Syringe	200000002150	
5.6.2	Manufactured item quantity	European	4.5 <g>	4.5 <100000110654>	
5.6.3	Manufactured dose form	European	Intramammary suspension	100000073893	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date – FR	National	22/09/2021		
5	**Packaged medicinal product (2)**	**European**			
5.1	Package description	European	Low density Polyethylene intramammary 120 syringe contain 4.5g mma ry suspensio		
5.1.1	Language	Eur an	nglish	100000072147	
5.2	Pack Size (structured values)	E opean	120 <syringe>	120 <200000002150>	
5.3	Package identifier	European		PCKID-41002	System generated
5.4	Legal stat of supply	Nat al			
5.5	**arketing uthorisat n ackage l el)**	**ational**			
5.5.1	Mar authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Syringe	200000002150	
5.6.2	Manufactured item quantity	European	4.5 <g>	4.5 <100000110654>	
5.6.3	Manufactured dose form	European	Intramammary suspension	100000073893	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.7	**Availability status**	**National**			
5.7.1	Country	National	France	100000000395	
5.7.2	Availability status – FR	National	Not marketed	100000072074	
5.7.3	Availability status date – FR	National	22/09/2021		

5. Poulvac Marek Diluent

This example illustrates a nationally authorised product with no active ingredient.

SPC Section 1 (Name of the veterinary medicinal product): *Poulvac Marek Diluent*

SPC Section 2 (Quantitative and Qualitative composition): *Not applicable (FR: Sans objet)*

SPC Section 6.5 Nature and composition of immediate packaging: *Bottles containing 200 ml (volume 250 ml), 400 ml (volume 500 ml) or 500 ml (volume 500 ml) of diluent; Bags containing 200 ml (volume 500 ml), 400 ml (volume 500 ml) or 1000 ml (volume 1000 ml) of diluent*

Country: Belgium

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		76a2ed95-5695-4bbc-81d5-6f66bdbf403a	System generated
1.4	Permanent identifier	National		*601232356574*	System generated
1.5	(Authorised) pharmaceutical form	European	Solvent for parenteral use	100000073881	
1.6	Legal status of supply	National	Veterinary Medicinal product subject to prescription	200000017698	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)	100000116059	
1.7.2	ATC vet code(s)	European	QI01AD03	100000119472	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1) - FR**	**National**			
1.8.1	Veterinary medicinal product name	National	Poulvac Marek Diluent		
1.8.2	Name Part	National			
1.8.3	**Country/Language**	**National**			
1.8.3.1	Country	National	Belgium	100000000337	
1.8.3.2	Language	National	French	100000072175	
1.8.2	Name Part	National			
1.8	**Veterinary medicinal product name (2) - NL**	**National**			
1.8.1	Veterinary medicinal product name	National	Poulvac Marek verdunnings middel		
1.8.3	**Country/Language**	**National**			
1.8.3.1	Country	National	Belgium	100000000337	
1.8.3.2	Language	National	Dutch	100000072169	
1.8.2	Name Part	National			
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	John Doe		This is not a real value as the content of the field is

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
					confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance (100000155057)		
1.10.3	QPPV Location	European		LOC-100001772	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - FR**	**National**			
1.11.1	(Attached document) identifier	National		1006	System generated
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	Belgium	100000000337	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	French	100000072175	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	be-spc-NP-BE- 1234-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*601232356574*	Using system generated ID
1.11	**Attached Document (2)**	**National**			
1.11.1	(Attached document) identifier	National		1007	System generated
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.11.4	(Attached document) Country	National	Belgium	100000000337	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	Dutch	100000072169	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	be-spc-NP-BE- 1234-nl.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*601237[illegible]574*	Using system generated ID
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing Business Operation**	**National**			
1.13.1	Manufacturer	National	Zoetis Manufacturing & Research Spain S.L.	LOC-100012170	
1.13.2	Manufacturing activity	European & National	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation/ registration/entitlement information**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National			
2.3	Country	National	Belgium	100000000337	
2.4	Responsible authority (organisation)	National	Federal Agency for Medicines	LOC-100000006	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
			and Health Products		
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	14/12/2009		
2.8	Product Owner (organisation)	National	Zoetis Belgium	LOC-100001772	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European			
2.12	Concerned member state	European			
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	NP-BE- [illegible]34		
2.13.2	Procedure type	European	Nation[illegible] procedu[illegible]	100000155062	
3	**Pharmaceutical Product**	**Eur[illegible]can**			
3.1	**Ingredient**	**E[illegible]ropea**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Rou[illegible] a[illegible]ion	Eu[illegible]pean	Intramuscular use	100000073600	
3.3	[illegible]arget speci[illegible]	European	Chickens	100000108935	
3.4	**Withdrawal period**	**European**			
3.4.3	Note	European	Zero day		
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredient (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.1	Substance	European	Water for injection	100000078023	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ Bottle	100000110662 / 200000002111	
4.3.2.1.1	Strength (presentation single value)	European	200/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominato	European			
4	**Ingredien (2)**	**Europea**			
4.1	Ingredient le	Eur ean	Active	100000072072	
4.3	**Sub ce**	**Eu pean**			
4.3.1	ubstance	uropean	Water for injection	100000078023	
4.3.2	**trength (q antitati e com ion)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ Bottle	100000110662 / 200000002111	
4.3.2.1.1	Strength (presentation single value)	European	400/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (3)**	**European**			
4.1	Ingredient role	European	Active	1[illegible]0000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Water for injection	[illegible]000078023	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ [illegible]ttle	[illegible]00000110662 / 200000002111	
4.3.2.1.1	Strength (presentation single value)	European	500/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (4)**	**European**			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Water for injection	100000078023	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ Bag	100000110662 / 200000002166	
4.3.2.1.1	Strength (presentation single value)	European	200/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (S**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Water for injection	100000078023	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ Bag	100000110662 / 200000002166	
4.3.2.1.1	Strength (presentation single value)	European	400/1		
4.3.2.2	Strength (concentration)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
4	**Ingredient (6)**	**European**			
4.1	Ingredient role	European	Activ	100[illegible]/2072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Wat[illegible]for injectio	[illegible]00000078023	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	Ml/ Bag	100000110662 / 200000002166	
4.3.2.1.1	Strength (presentation single valu	European	1000/1		
4.3.2.2	Strength (c[illegible]tion)	Eur[illegible]pean			
4.3.2.2.1	[illegible]trength [illegible]concentrati[illegible]ngle value)	[illegible]uropean			
4.3.3	**R[illegible]erence Stre[illegible]**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product (1)**	**National**			
5.1	Package description (FR)	National	Flacons en verre borosilicaté de type II contenant 200 ml (volume 250 ml) de diluant		
5.1.1	Language	National	French	100000[illegible]2175	
5.1	Package description (NL)	National	Type II borosilicaat glazen flessen bevattende 200 ml (volume 250 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bottle>	- <200000002111>	
5.3	Package identifier	European		PCKID-91001	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552151		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bottle	200000002111	
5.6.2	Manufactured item quantity	European	200 <ml>	200 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.7	**Availability status**	**National**			
5.7.1	Country	National	Belgium	100000000337	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		
5	**Packaged medicinal product (2)**	**National**			
5.1	Package description (FR)	National	Flacons en verre borosilicaté de type II contenant 400 ml (volume 500 ml) de diluant		
5.1.1	Language	National	French	100000[illegible]2175	
5.1	Package description (NL)	National	Type II borosilicaat glazen flessen bevattende 400 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	10[illegible]000072169	
5.2	Pack Size (structured values)	European	1 <bottle>	1 <200000002111>	
5.3	Package identifier	European		PCKID-91002	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552152		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bottle	200000002111	
5.6.2	Manufactured item quantity	European	400 <ml>	400 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.7	**Availability status**	**National**			
5.7.1	Country	National	Belgium	100000000337	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		
5	**Packaged medicinal product (3)**	**National**			
5.1	Package description (FR)	National	Flacons en verre borosilicaté de type II contenant 500 ml (volume 500 ml) de diluant		
5.1.1	Language	National	French	100000[illegible]2175	
5.1	Package description (NL)	National	Type II borosilicaat glazen flessen bevattende 500 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	10[illegible]000072169	
5.2	Pack Size (structured values)	European	1 <bottle>	1 <200000002111>	
5.3	Package identifier	European		PCKID-91003	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552153		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bottle	200000002111	
5.6.2	Manufactured item quantity	European	500 <ml>	500 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.72	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5	**Packaged medicinal product (4)**	**National**			
5.1	Package description (FR)	National	Sachets en chlorure de polyvinyle (PVC) contenant 200 ml (volume 500 ml) de diluant		
5.1.1	Language	National	French	100000072175	
5.1	Package description (NL)	National	Polyvinyl chloride (PVC) zakken bevattende 200 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bag>	1 <200000002166>	
5.3	Package identifier	European		PKID-91004	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552154		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bag	200000002166	
5.6.2	Manufactured item quantity	European	200 <ml>	200 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.7	**Availability status**	**National**			
5.7.1	Country	National	Belgium	100000000337	
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5	**Packaged medicinal product (5)**	**National**			
5.1	Package description (FR)	National	Sachets en chlorure de polyvinyle (PVC) contenant 400 ml (volume 500 ml) de diluant		
5.1.1	Language	National	French	100000072175	
5.1	Package description (NL)	National	Polyvinyl chloride (PVC) zakken bevattende 400 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bag>	1 <200000002166>	
5.3	Package identifier	European		PCID-91005	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552155		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bag	200000002166	
5.6.2	Manufactured item quantity	European	400 <ml>	400 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.7	**Availability status**	**National**			
5.7.1	Country	National	Belgium	100000000337	
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5	**Packaged medicinal product (6)**	**National**			
5.1	Package description (FR)	National	Sachets en chlorure de polyvinyle (PVC) contenant 1000 ml (volume 1000 ml) de diluant		
5.1.1	Language	National	French	100000072175	
5.1	Package description (NL)	National	Polyvinyl chloride (PVC) zakken bevattende 1000 ml (volume 1000 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bag>	1 <200000002166>	
5.3	Package identifier	European		CKID-91006	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552156		
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Bag	200000002166	
5.6.2	Manufactured item quantity	European	1000 <ml>	1000 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
5.7	**Availability status**	**National**			
5.7.1	Country	National	Belgium	100000000337	
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	20/10/2021		

6. Amoxicillin 150mg/ml maymo

SPC Section 1 (Name of the veterinary medicinal product): Amoxicillin 150mg/ml maymo solution for injection

SPC Section 2 (Quantitative and Qualitative composition): Each ml contains: Active substance Amoxicillin 150 mg (equivalent to amoxicillin trihydrate 172 mg).

SPC Section 6.5 (Nature and composition of immediate packaging): Vial of 100ml Vial of 250ml

Reference Member State: Ireland

Concerned Member State: Austria, Belgium, France

This example illustrates a complex withdrawal period section and the active substance is expressed as a reference strength.

The following table illustrates how the information should be provided in the common data set by the RMS and in the national data set by CMS.

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product Identifier	European		43a2ed95-5695-4bbc-81d5-6f66bdbf403a	System generated
1.4	Permanent identifier	National		*601236756524*	System generated for RMS
1.4	Permanent identifier	National		*604332356524*	System generated for CMS
1.5	(Authorised) pharmaceutical form	European	Solution for injection	100000073863	
1.6	Legal status of supply	National	Veterinary medicinal product subject to veterinary prescription	200000017698	
1.7	**Product Classification**	**European**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.7.1	Legal basis	European	Generic (abridged application) - art 13(1)	100000116061	
1.7.2	ATC vet code(s)	European	QJ01CA04	100000120360	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1) - EU**	**European**			
1.8.1	Veterinary medicinal product name	European	Amoxicillin 150mg/ml maymo solution for injection		
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	10[illegible]0000038[illegible]	
1.8.3.2	Language	European	English	100000072147	
1.8.2	Name Part	National			
1.8	**Veterinary medicinal product name (2) - FR**	**Na[illegible]nal**			
1.8.1	Veterinary medicinal product name	National	BIMOXYL LA 150 MG/ML SUSPENSION INJECTABLE POUR BOVINS OVINS ET PORCINS		
1.8.3	**C[illegible]ntry Language**	**National**			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	
1.8.2	Name Part	National			
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.10.1	QPPV Name	European	Dr. John Smith		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC-100010593	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European			
1.11.2	(Attached document) status	European	Current	"current"	
1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc- IE-V-0362-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*601236756524* *604332356524*	Using system generated IDs for RMS & CMS products
1.11	**Attached Document (2) - FR**	**National**			
1.11.1	(Attached document) identifier	National			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1.11.2	(Attached document) status	National	Current	"current"	
1.11.3	(Attached document) type	National	SPC	100000155532	
1.11.4	(Attached document) Country	National	France	100000000395	
1.11.5	(Attached document) content type	National	pdf	"application/pdf"	
1.11.6	(Attached document) Language	National	French	100000072175	
1.11.7	(Attached document) content	National	Physical document		
1.11.8	(Attached document) title	National	fr-spc- IE-V-0362-001-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		*60433[illegible]524*	Using system generated ID for CMS product
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	[illegible] product identifier	National			
1.13	**Manufacturing Business Operation**	**European**			
1.13.1	Manufacturer	European	BIMEDA ANIMAL HEALTH LIMITED	LOC-100019989	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation /registration /entitlement information - FR**	**European & National**			

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/1009923 4/2017		
2.3	Country	National	French Republic	100000000395	
2.4	Responsible authority (organisation)	National		LOC-100045741	
2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	24/01/2017		
2.8	Product Owner (organisation)	National	Laboratories Maymo S.A.	LOC-100010593	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Ireland	100000000427	
2.12	Concerned member state	European	Austria	100000000330	
2.12	Concerned member state	European	France	100000000395	
2.12	Concerned member state	European	Belgium	100000000337	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	IE/V/0362/001		
2.13.2	Procedure type	European	Decentralised procedure	100000155060	
3	**Pharmaceutical Product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration	European	Intramuscular use	100000073600	
3.3	Target species (1)	European	Cattle	100000108893	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
3.4	**Withdrawal period (1)**	**European**			
3.4.3	Note	European	Meat and offal: 18 days. Milk: 72 hours.		
3.3	Target species (2)	European	Dog	100000108988	
3.3	Target species (3)	European	Pig	100000109151	
3.4	**Withdrawal period (3)**	**European**			
3.4.3	Note	European	Meat and offal: 21 days.		
3.3	Target species (4)	European	Sheep	10000[illegible]10902[illegible]	
3.4	**Withdrawal period (4)**	**European**			
3.4.3	Note	European	Meat and offal: 21 days. N[illegible] authorised[illegible] in sheep producing milk for human co[illegible]ptio n.		
3.5	Administrable dose form	E[illegible]an	Pharmaceuti cal dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
4	**Ingredie[illegible]**	**Eu[illegible]pean**			
4.1	I[illegible]nt ro[illegible]	E[illegible]opean	Active	100000072072	
4.3	**Substan[illegible]**	**European**			
4.3.1	Substance	European	Amoxicillin trihydrate	100000092629	
4.3.2	**St[illegible]n (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	mg /ml	100000110656/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	172/1		

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European	amoxicillin	100000091596	
4.3.3.1.1	Reference strength (presentation)	European	mg / ml	100000110656/ 100000110662	
4.3.3.1.2	Reference strength (Presentation single value)	European	150/1		
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product (1)**	**European & National**			
5.1	Package description - EU	European	Vial of 100 ml		
5.1.1	Language	European	English	100000072147	
5.1	Package description - FR	National	Boîte de 1 flacon de 100 ml		
5.1.1	Language	National	French	100000072175	
5.2	Pack Size (structured values)	European	1 <vial>	1 <200000002158>	
5.3	Package identifier	European		PCKID-45640	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <100000110662>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.7	**Availability status**	**National**			
5.7.1	Country	National	France		
5.7.2	Availability status - FR	National	Not marketed	100000072074	
5.7.3	Availability status date - FR	National	30/06/2021		
5	**Packaged medicinal product (2)**	**European**			
5.1	Package description - EU	European	Vial of 250 ml		
5.1.1	Language	European	English	100000[illegible]7214	
5.1	Package description - FR	National	Boîte de 1 flacon de 250 ml		
5.1.1	Language	National	French	1[illegible]0072175	
5.2	Pack Size (structured values)	European	1 <vial>	1 <20000[illegible]0215 8>	
5.3	Package identifier	European		PCK[illegible]-45641	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (2)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	250 <ml>	250 <10000011066 2>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
5.7	**Availability status**	**National**			
5.7.1	Country	National	France		
5.7.2	Availability status - FR	National	Not marketed	100000072074	

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
5.7.3	Availability status date - FR	National	30/06/2021		

7. Pluset

SPC Section 1 (Name of the veterinary medicinal product):

PLUSET 500 IU/500 IU powder and solvent for solution for injection for cattle [PL]

PLUSET vet 500 IU/500 IU Powder and solvent for solution for injection for bovine [FI]

PLUSET 500 IU/500 IU Powder and solvent for solution for injection Follicle stimulating hormone (FSHp), Luteinizing hormone (LHp) [DE]

SPC Section 2 (Quantitative and Qualitative composition):

One vial of lyophilized product contains:

Active substances:

- Follicle stimulating hormone (FSHp) ..... 500 IU

- Luteinizing hormone (LHp) ..... 500 IU

One vial of solvent contains:

- Chlorocresol ..... 0.021 g

- Sterile, pyrogen-free, normal saline to ..... 21 ml

Each ml of reconstituted solution contains:

Active substance:

Follicle stimulating hormone (FSHp) ..... 50 IU

Luteinising hormone (LHp) ..... 50 IU

Excipients:

Chlorocresol ..... 1 mg

Sterile, pyrogen-free, normal saline to ..... 1 ml

Section 6.5 (Nature and composition of immediate packaging):

Container for the lyophilised product:

- Vial of colourless neutral glass (type 1) Capacity: 10 ml. Provided with bromobutyl and silicate stopper and aluminium cap flip off seal.

Container for the diluent:

- Vial of colourless neutral glass (type 1) Capacity: 21 ml. With rubber penitype stopper of grey colour and aluminium cap flip off seal.

- Cardboard box with 2 glass vials of 10 ml of lyophilised product and 1 glass vial of 21 ml of diluent.

Reference Member State: *Italy*

This example illustrates a complex pharmaceutical product composition where reconstituted active ingredients are to be provided with the appropriate strengths; a complex package description with different numbers of manufactured items is also illustrated.

NOTE 1: In order to provide an example on how manufactured composition (manufactured ingredients and strengths) may differ from the pharmaceutical product section, this examples also include manufactured ingredient information despite this is optional to be submitted for legacy data product.

NOTE 2: please note the example is for illustration only and the values and related codes may not be real and completed with all the applicable information.

The following table illustrates how the information should be provided in the common and national data set by the RMS.

Vet EU IG Ref.	UPD data element name	European / National	Value	Value code	Note
1	**Veterinary medicinal product**	**European**			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data
1.3	Product identifier	European		43a2fd95-5695-4bbc-81d5-7f66bdbf876s	System generated
1.4	Permanent identifier	National		*601236756723*	System generated for RMS
1.5	(Authorised) pharmaceutical form	European	Powder and solvent for solution for injection	100000073868	
1.6	Legal status of supply	National	Veterinary medicinal product subject to veterinary prescription	200000017698	

1.7	**Product Classification**	**European**			
1.7.1	Legal basis	European	Full application - New active substance (Art.12(3) Dir 2001/82/EC)	100000116059	
1.7.2	ATC vet code(s)	European	QG03GA90	100000119190	
1.7.3	ATC vet code(s) flag	European			
1.8	**Veterinary medicinal product name (1) - EU**	**European**			
1.8.1	Veterinary medicinal product name	European	PLUSET 500 IU/500 IU powder and solvent for solution for injection		
1.8.3	**Country/Language**	**European**			
1.8.3.1	Country	European	EU	10000[illegible]590	
1.8.3.2	Language	European	English	100[illegible]072147	
1.8.2	Name Part	National			
1.10	**Pharmacovigilance Contact (QPPV)**	**European**			
1.10.1	QPPV Name	European	Dr. Mario Rossi		This is not a real value as the content of the field is confidential in the UPD access policy
1.10.2	QPPV Role	European	Qualified Person in the EEA for Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC-100006613	This is not a real value as the content of the field is confidential in the UPD access policy
1.11	**Attached Document (1) - EU**	**European**			
1.11.1	(Attached document) identifier	European			
1.11.2	(Attached document) status	European	Current	"current"	

1.11.3	(Attached document) type	European	SPC	100000155532	
1.11.4	(Attached document) Country	European	EU	100000000390	
1.11.5	(Attached document) content type	European	pdf	"application/pdf"	
1.11.6	(Attached document) Language	European	English	100000072147	
1.11.7	(Attached document) content	European	Physical document		
1.11.8	(Attached document) title	European	eu-spc-it-v-0117-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		*60123675672*	[illegible] system generated [illegible]s for RMS [illegible] products
1.12	**Product cross-reference**	**European & National**			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
1.13	**Manufacturing Business Operation**	**European**			
1.13.1	Manufacturer	European	Laboratorios Calier S.A.	LOC-100006613	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
2	**Authorisation /registration /entitlement information - IT**	**European & National**			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	AIC4567389		
2.3	Country	National	Italy	100000000430	
2.4	Responsible authority (organisation)	National	Italian Medicines Agency	LOC-100000033	

2.5	Authorisation status	National	Valid	100000072099	
2.7	Marketing authorisation date	National	31/01/2017		
2.8	Product Owner (organisation)	National	Laboratorios Calier S.A.	LOC-100010456	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Ireland	100000000427	
2.12	Concerned member state	European	France	100000000395	
2.12	Concerned member state	European	Belgium	100000000[illegible]37	
2.13	**Marketing authorisation procedure**	**European**			
2.13.1	Procedure number	European	IT/V/0117/001		
2.13.2	Procedure type	European	Mutual Recognition	100[illegible]01550[illegible]1	
3	**Pharmaceutical Product**	**European**			
3.1	**Ingredient**	**European**			The user will need to provide the ingredient based on the ones created in the Ingredient section 4
3.2	Route of administration	[illegible]ropean	Intramuscular use	100000073600	
3.3	Target species (1)	European	Cattle	100000108893	
3.4	**Withdrawal period (1)**	**European**			
3.4.3	[illegible]	European	Cattle: meat and offal: Zero days milk: Zero hours		
4	**Ingredient (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Follicle-stimulating hormone	100000090586	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			

4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	IU /ml	100000110671/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	50/ 1		
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Luteinising hormone	100000124465	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	IU /ml	100000110671/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	50/ 1		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5	**Packaged medicinal product**	**European & National**			
5.1	Package description - EU	European	Cardboard box with 2 glass vials of 10 ml of lyophilised product and 1 glass vial of 21 ml of diluent.		
5.1.1	Language	European	English	100000072147	

5.2	Pack Size (structured values)	European	2 <vial>	1 <200000002158>	
5.3	Package identifier	European		PCKID-85632	System generated
5.4	Legal status of supply	National			
5.5	**Marketing authorisation (package level)**	**National**			
5.5.1	Marketing authorisation number (package level)	National			
5.6	**Manufactured item (1)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	10 <ml>	10 <100000110662>	
5.6.3	Manufactured dose form	European	Lyophilisate for solution for injection	100000073873	
4	**Ingredient (1) - Manufactured item (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Follicle-stimulating hormone	100000090586	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	IU /ml	100000110671/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	500/ 1		
4	**Ingredient (2) - Manufactured item (1)**	**European**			
4.1	Ingredient role	European	Active	100000072072	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Luteinising hormone	100000124465	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			

4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	IU /ml	100000110671/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	500/1		
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
5.6	**Manufactured item (2)**	**European**			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	21 <ml>	21 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
4	**Ingredient (1) - Manufactured item (2)**	**European**			
4.1	Ingredient role	European	Excipient	100000072082	
4.3	**Substance**	**European**			
4.3.1	Substance	European	Chlorocresol	100000081847	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			
4.3.2.2	Strength (concentration)	European	g /ml	100000110654/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	0.021/ 1		
4	**Ingredient (2)**	**European**			
4.1	Ingredient role	European	Excipient	100000072082	
4.3	**Substance**	**European**			

4.3.1	Substance	European	STERILE PYROGEN-FREE ISOTONIC NACL SOLUTE (0.9% W / V)	100000138946	
4.3.2	**Strength (quantitative composition)**	**European**			
4.3.2.1	Strength (presentation)	European	ml/ vial	100000110662/ 200000002158	
4.3.2.1.1	Strength (presentation single value)	European	21/ 1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
4.3.3	**Reference Strength**	**European**			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			
4.3.3.1.2	Reference strength (Presentation single value)	European			
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentrati - denomi ator	ıropea			
5.7	**Availab ity status**	**Na ional**			
5.7.1	C y	N tional	Italy	100000000430	
5.7.2	Availabi y status - I	ational	Not marketed	100000072074	
5.7.3	Availability tatus dat - I	National	30/06/2021		