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## 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 1.1

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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## Table of contents

Scope of this guidance.....	3
1. Mutual Recognition Procedure: Drontal .....	4
1.1. Drontal submission by the RMS.....	4
1.2. Drontal submission by the CMS.....	14
2. Boflox.....	27
3. Hipracox .....	46
4. Multishield.....	62
5. Poulvac Marek Diluent .....	74
6. Amoxicillin 150mg/ml maymo.....	93

## 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);
- 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 Technical Specification;
- 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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
1.1	Domain	European	Veterinary use	100000000013	

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		77a2ed95-5695-4bbc-81d5-6f66bdbf403a	<i>System generated</i>
1.4	Permanent identifier (1) - DE	National		601232356524	<i>System generated for RMS product</i>
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	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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	QP52AA51	100000122207	
1.7.3	ATC vet code(s) flag	European			
<b>1.8</b>	<b>Veterinary medicinal product name (1)</b>	<b>European &amp; National</b>			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Film-coated Tablet for Cats		
1.8.2	Name Part	European & National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
1.8.3.2	Language	European	English	100000072147	
<b>1.8</b>	<b>Veterinary medicinal product name (2) - DE</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Filmtablette für Katzen		
1.8.2	Name Part	European & National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	Germany	100000000403	
1.8.3.2	Language	European	German	100000072178	
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
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
<b>1.11</b>	<b>Attached Document (2) - DE</b>	<b>National</b>			
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"	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
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		
1.11.9	(Attached document) related veterinary medicinal products	National	PEI00001	601232356524	Using system generated ID for RMS product
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European		LOC-100020435	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	DE-23456	DE-23456	



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
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	
2.12	Concerned member state (1)	European	France	100000000395	
2.12	Concerned member state (2)	European	Spain	100000000529	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	DE/V/0101/001	DE/V/0101/001	
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
3.3	Target species	European	Cats	100000109056	
<b>3.4</b>	<b>Withdrawal period</b>	<b>European</b>			
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
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Pyrantel embonate	100000089059	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European	Pyrantel	100000080865	
4.3.3.1.1	Reference strength (presentation)	European	Mg/Tablet	100000110655/ 200000002152	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
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			
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Praziquantel	100000147274	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European</b>			
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 <200000002109 >	
5.3	Package identifier	European		<i>PCKID-45632</i>	<i>System generated</i>
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7.</b>	<b>Availability status</b>	<b>National</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
5.7.1	Country	National	Germany	100000000403	
5.7.2	Availability status	National	Not marketed	100000072074	
5.7.3	Availability status date	National	11/09/2021	11/09/2021	
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European</b>			
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	
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	<i>PCKID-45633</i>	<i>System generated</i>
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Tablet	200000002109	
5.6.2	Manufactured item quantity	European	20 <tablet>	20 <100000073664 >	
5.6.3	Manufactured dose form	European	Tablet	100000073664	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
5.7.2	Availability status - DE	National	Not marketed	100000072074	
5.7.3	Availability status date - DE	National	11/09/2021	11/09/2021	

### 1.2. Drontal submission by the CMS

France, as CMS, submits the national data set for Drontal 230/20 mg Film-coated Tablet for Cats in UPD providing the following data:

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
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
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	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
1.6	Legal status of supply (2) - FR	National	Veterinary Medicinal product subject to prescription	200000017698	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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	QP52AA51	100000122207	
1.7.3	ATC vet code(s) flag	European			
<b>1.8</b>	<b>Veterinary medicinal product name (1)</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Film-coated Tablet for Cats		
1.8.2	Name Part	European & National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
<b>1.8</b>	<b>Veterinary medicinal product name (2) - DE</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Drontal 230/20 mg Filmtablette für Katzen		
1.8.2	Name Part	European & National			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	Germany	100000000403	
1.8.3.2	Language	European	German	100000072178	
<b>1.8</b>	<b>Veterinary medicinal product name (3) - FR</b>	<b>European</b>			
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			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	France	100000000395	
1.8.3.2	Language	European	French	100000072175	
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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 Pharmacovigilance	100000155057	
1.10.3	QPPV Location	European		LOC-100019643	This is not a real value as the content



Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
					of the field is confidential in the UPD access policy
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			
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		
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
<b>1.11</b>	<b>Attached Document (2) - DE</b>	<b>National</b>			<b>Document not seen by CMS in their product</b>
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	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
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
<b>1.11</b>	<b>Attached Document (3) - FR</b>	<b>National</b>			
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	
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		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
1.11.9	(Attached document) related veterinary medicinal products	National		603235612987	Using system generated ID for CMS product
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European		LOC-100020435	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information (1) - DE</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	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	100000000322	
2.12	Concerned member state (2)	European	Spain	100000000324	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	DE/V/0101/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>2</b>	<b>Authorisation/registration/entitlement information (2) - FR</b>	<b>European &amp; National</b>			
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	

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	100000000322	
2.12	Concerned member state (2)	European	Spain	100000000324	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	DE/V/0101/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	
<b>3.4</b>	<b>Withdrawal period</b>	<b>European</b>			
3.4.3	Note	European			

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
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Pyrantel embonate	100000089059	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Praziquantel	100000147274	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European</b>			
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		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
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		PCKID-45632	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European</b>			



Vet EU IG Ref.	UPD data element name	European/National	Value	Value Code	Note
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 plaquettes de 20 comprimés	
5.1.1	Language (2.3) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	40 <tablet>	40 <200000002109>	
5.3	Package identifier	European		PCKID-45633	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Tablet	200000002109	
5.6.2	Manufactured item quantity	European	20 <Tablet>	20 <100000073664>	
5.6.3	Manufactured dose form	European	Tablet	100000073664	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
5.7.1	Country	National	Germany	100000000403	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value Code	Note
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	
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 stopper 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 State: *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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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		602323565246	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 prescription	200000017698	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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			
<b>1.8</b>	<b>Veterinary medicinal product name (1)</b>	<b>European</b>			
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			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.8.3.2	Language	European	English	100000072147	
<b>1.8</b>	<b>Veterinary medicinal product name (2)</b>	<b>National</b>			
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			
<b>1.8.3</b>	<b>Country/Language</b>	<b>National</b>			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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		LOC-100019643	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
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			
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
<b>1.11</b>	<b>Attached Document (2) - FR</b>	<b>National</b>			
1.11.1	(Attached document) identifier	National		1024	System Generated
1.11.2	(Attached document) status	National	Current	200000005004	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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- ES-V-0190-001- fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		602323565246	Using system generated ID for CMS product
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation (1)</b>	<b>European</b>			
1.13.1	Manufacturer	European	INDUSTRIAL VETERINARIA-Spain	LOC-100019643	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>1.13</b>	<b>Manufacturing Business Operation (2)</b>	<b>European</b>			
1.13.1	Manufacturer	European	KELA- Belgium	LOC-100019925	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>1.13</b>	<b>Manufacturing Business Operation (3)</b>	<b>European</b>			
1.13.1	Manufacturer	European	ANIMEDICA HERSTELLUNGS-Germany	LOC-100022291	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information (FR)</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/5589281 8/2013		
2.3	Country	National	France	100000000395	
2.4	Responsible authority (organisation)	National		LOC-100045741	



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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	
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	100000000406	
2.12	Concerned member state (8)	European	Ireland	100000000427	
2.12	Concerned member state (10)	European	Italy	100000000430	
2.12	Concerned member state (11)	European	Hungary	100000000421	
2.12	Concerned member state (12)	European	Lithuania	100000000450	
2.12	Concerned member state (13)	European	Luxembourg	100000000451	
2.12	Concerned member state (14)	European	Netherlands	100000000478	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
2.12	Concerned member state (15)	European	Poland	100000000500	
2.12	Concerned member state (16)	European	Portugal	100000000501	
2.12	Concerned member state (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	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	ES/V/0190/001		
2.13.2	Procedure type	European	Decentralised procedure	100000155060	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	100000073600	
3.3	Target species (1)	European	Cattle	100000108893	
<b>3.4</b>	<b>Withdrawal period (1)</b>	<b>European</b>			
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 (2)	European	Subcutaneous use	100000073633	
3.3	Target species (2)	European	Cattle	100000108893	
<b>3.4</b>	<b>Withdrawal period (2)</b>	<b>European</b>			
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) 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	100000108893	
<b>3.4</b>	<b>Withdrawal period (3)</b>	<b>European</b>			
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) 2mg/kg for 3 days (IV/IM/SC)		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
			Meat and offal 6 days 3 days 6 days Milk 36 hours 72 hours 36 hours		
3.2	Route of administration (4)	European	Intramuscular use	100000073600	
3.3	Target species (4)	European	Pig	100000109151	
<b>3.4</b>	<b>Withdrawal period (4)</b>	<b>European</b>			
3.4.3	Note	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
<b>4</b>	<b>Ingredient</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Marbofloxacin	100000081743	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European			
4.3.3.1.1	Reference strength (presentation)	European			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European</b>			
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			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (1)</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <100000110662>	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European</b>			
5.1	Package description (2.1) - EU	European	Carton box with 1 vial of 250 ml		
5.1.1	Language (2.1) - EU	European	English	100000072147	
5.1	Package description (2.2)-FR	National	Boîte de 1 flacon de 250 ml		
5.1.1	Language (2.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	1 <Vial>	1 <20000000215 8>	
5.3	Package identifier	European		PCKID-30002	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (2)</b>	<b>European</b>			
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	250 ml	250 <10000011066 2>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (3)</b>	<b>European</b>			
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	100000072147	
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 <20000000215 8>	
5.3	Package identifier	European		PCKID-30003	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (3)</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 ml	100 <10000011066 2>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (4)</b>	<b>European</b>			
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 <20000000215 8>	
5.3	Package identifier	European		PCKID-30004	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (4)</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (5)</b>	<b>European</b>			
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	
5.2	Pack Size (structured values)	European	10 <vial>	10 <20000000215 8>	
5.3	Package identifier	European		PCKID-30005	System generated
5.4	Legal status of supply	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (5)</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <10000011066 2>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (6)</b>	<b>European</b>			
5.1	Package description (6.1) - EU	European	Carton box with 10 vials of 250 ml		
5.1.1	Language (6.1) - EU	European	English	100000072147	
5.1	Package description (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 <20000000215 8>	
5.3	Package identifier	European		PCKID-30006	System generated

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (6)</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (7)</b>	<b>European</b>			
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	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.2	Pack Size (structured values)	European	12 <vial>	12 <20000000215 8>	
5.3	Package identifier	European		PCKID-30007	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (7)</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <10000011066 2>	
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (8)</b>	<b>European</b>			
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	100000072147	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.1	Package description (8.2) - FR	National	Boîte de 12 flacons de 250 ml		
5.1.1	Language (8.2) - FR	National	French	100000072175	
5.2	Pack Size (structured values)	European	12 <vial>	12 <20000000215 8>	
5.3	Package identifier	European		PCKID-30008	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (8)</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		

### 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 ml dose of vaccine contains the following numbers of sporulated oocysts derived from five precocious attenuated 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 – 325 \**

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 of 1,000 doses.*

*Cardboard box with 10 vials 50 ml of 5,000 doses.*

This example illustrates an immunological.

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. <sup>1</sup>

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
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		73a2ed95-5695-4bbc-81d5-6f66bdf403a	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	200000017698	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
1.7.1	Legal basis	European	Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)	100000116058	
1.7.2	ATC vet code(s)	European	QI01AN01	100000119506	

<sup>1</sup> 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
1.7.3	ATC vet code(s) flag	European			
<b>1.8</b>	<b>Veterinary medicinal product name - EU</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Hipracox Broilers Oral suspension for chicken		
1.8.2	Name Part	European & National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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-100014177	This is not a real value as the content of the field is confidential in the UPD access policy
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.11.1	(Attached document) identifier	European	127890	127890	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
<b>1.11</b>	<b>Attached Document (2) - FR</b>	<b>National</b>			
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"	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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- ES-V-0327-001-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		601232356534	Using system generated ID for CMS
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European		LOC-100010373	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration /entitlement information - FR</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing Authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/2510096 9/2008		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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-100014177	
2.9	Source wholesale distributor (organisation)	National			
2.10	Destination wholesale distributor (organisation)	National			
2.11	Reference member state	European	Spain	100000000324	
2.12	Concerned member state (1)	European	Belgium	100000000318	
2.12	Concerned member state (2)	European	Denmark	100000000331	
2.12	Concerned member state (3)	European	France	100000000322	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	ES/V/0327/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
3.3	Target species	European	Broiler	100000108934	
<b>3.4</b>	<b>Withdrawal period</b>	<b>European</b>			
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
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Eimeria acervulina, strain 003, Live	300000008520	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Eimeria maxima, strain 013, Live	300000008559	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (3)</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Eimeria mitis, strain 006, Live	300000008486	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (4)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Eimeria praecox, strain 007	300000008554	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (5)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Eimeria tenella, strain 004	300000008493	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European &amp; National</b>			
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 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>	1 <20000000215 8>	
5.3	Package identifier	European		PCKID- 33001	System generated
5.4	Legal status of supply	National			



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European &amp; National</b>			
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,		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
			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>	1 <200000002158>	
5.3	Package identifier	European		PCKID- 33002	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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	30/08/2021		
<b>5</b>	<b>Packaged medicinal product (3)</b>	<b>European</b>			
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-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	10 <vial>	10 <200000002158>	
5.3	Package identifier	European		PCKID- 33003	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (4)</b>	<b>European</b>			
5.1	Package description	European	Cardboard box with 10 vials of 50 ml with 5,000 doses, 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, Eimeria praecox, strain 007, Eimeria tenella, strain 004		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.1.1	Language	European & National	English	100000072147	
5.2	Pack Size (structured values)	European	10 <vial>	10 <200000002158>	
5.3	Package identifier	European		PCKID- 33004	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		

## 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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
1.1	Domain	European	Veterinary use	100000000013	
1.2	Product record status	European	Current	200000005004	The value will be "Current" for all legacy data

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
1.7.1	Legal basis	European	Generic application (Article 13(1) of Directive No 2001/82/EC)	100000116061	
1.7.2	ATC vet code(s)	European	QJ51RC22	100000120837	
1.7.3	ATC vet code(s) flag	European			
<b>1.8</b>	<b>Veterinary medicinal product name (1) - EU</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Multishield DC Intramammary Suspension for Cows		
1.8.2	Name Part	European			
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
1.8.3.2	Language	European	English	100000072147	
<b>1.8</b>	<b>Veterinary medicinal product name (2) - FR</b>	<b>National</b>			
1.8.1	Veterinary medicinal product name	National	MULTISHIELD DC SUSPENSION INTRAMAMMAIRE POUR VACHES		
1.8.2	Name Part	National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>National</b>			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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	
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
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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-IE-V-0277-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		601232356554 609876356556	Using system generated IDs for RMS & CMS
<b>1.11</b>	<b>Attached Document (2) - FR</b>	<b>National</b>			
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"	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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-0277-001-fr.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		601232356534	System generated for CMS
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European		LOC-100014156	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information - FR</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/94732588/2013		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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		
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	100000000395	
2.12	Concerned member state (3)	European	Germany	100000000403	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	IE/V/0277/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			
3.2	Route of administration	European	Intramammary use	100000073599	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
3.3	Target species	European	Cow	100000108888	
<b>3.4</b>	<b>Withdrawal period</b>	<b>European</b>			
3.4.3	Note	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.		
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Neomycin sulphate	100000090029	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
4.3.2.2.1	Strength (concentration single value)	European			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European	Neomycin	100000090456	
4.3.3.1.1	Reference strength (presentation)	European	UI/ syringe	100000110671/ 200000002150	
4.3.3.1.2	Reference strength (Presentation single value)	European	70 000		
4.3.3.2	Reference strength (concentration)	European			
4.3.3.2.1	Reference strength (concentration) - denominator	European			
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Penethamate Hydriodide	100000079773	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.3.1	Reference (Active) Substance	European	Penethamate	100000079753	
4.3.3.1.1	Reference strength (presentation)	European	Mg/ Syringe	100000110655/ 200000002150	
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			
<b>4</b>	<b>Ingredient (3)</b>				
4.1	Ingredient role	Active	100000072072		
<b>4.3</b>	<b>Substance</b>				
4.3.1	Substance	Procaine Benzylpenicillin	100000090112		
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>				
4.3.2.1	Strength (presentation)	Mg/ Syringe	100000110655/ 200000002150		
4.3.2.1.1	Strength (presentation single value)	400/1			
4.3.2.2	Strength (concentration)				
4.3.2.2.1	Strength (concentration single value)				
<b>4.3.3</b>	<b>Reference Strength</b>				
4.3.3.1	Reference (Active) Substance	Benzylpenicillin	100000091070		
4.3.3.1.1	Reference strength (presentation)	Mg/ Syringe	100000110655/ 200000002150		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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				
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European</b>			
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	Pack Size (structured values)	European	24 <syringe>	24 <200000002150>	
5.3	Package identifier	European		PCKID-41001	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Syringe	200000002150	
5.6.2	Manufactured item quantity	European	4.5 <g>	4.5 <100000110654>	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.3	Manufactured dose form	European	Intramammary suspension	100000073893	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European</b>			
5.1	Package description	European	Low density Polyethylene intramammary 120 syringe, containing 4.5g intramammary suspension.		
5.1.1	Language	European	English	100000072147	
5.2	Pack Size (structured values)	European	120 <syringe>	120 <200000002150>	
5.3	Package identifier	European		PCKID-41002	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Syringe	200000002150	



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.2	Manufactured item quantity	European	4.5 <g>	4.5 <100000110654>	
5.6.3	Manufactured dose form	European	Intramammary suspension	100000073893	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
1.1	Domain	European	Veterinary use	10000000013	
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	

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	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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			
<b>1.8</b>	<b>Veterinary medicinal product name (1) - FR</b>	<b>National</b>			
1.8.1	Veterinary medicinal product name	National	Poulvac Marek Diluent		
1.8.2	Name Part	National			
<b>1.8.3</b>	<b>Country/Language</b>	<b>National</b>			
1.8.3.1	Country	National	Belgium	100000000337	
1.8.3.2	Language	National	French	100000072175	
1.8.2	Name Part	National			
<b>1.8</b>	<b>Veterinary medicinal product name (2) - NL</b>	<b>National</b>			
1.8.1	Veterinary medicinal product name	National	Poulvac Marek verdunningsmiddel		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
<b>1.8.3</b>	<b>Country/Language</b>	<b>National</b>			
1.8.3.1	Country	National	Belgium	100000000337	
1.8.3.2	Language	National	Dutch	100000072169	
1.8.2	Name Part	National			
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
1.10.1	QPPV Name	European	John Doe		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-100001772	This is not a real value as the content of the field is confidential in the UPD access policy
<b>1.11</b>	<b>Attached Document (1) - FR</b>	<b>National</b>			
1.11.1	(Attached document) identifier	National		1006	System generated

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	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
<b>1.11</b>	<b>Attached Document (2)</b>	<b>National</b>			
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	
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		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
1.11.8	(Attached document) title	National	be-spc-NP-BE-1234-nl.pdf		
1.11.9	(Attached document) related veterinary medicinal products	National		601232356574	Using system generated ID
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>National</b>			
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	
<b>2</b>	<b>Authorisation/registration/entitlement information</b>	<b>European &amp; National</b>			
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 and Health Products	LOC-100000006	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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			
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	NP-BE- 1234		
2.13.2	Procedure type	European	National procedure	100000155062	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	European	Chickens	100000108935	
<b>3.4</b>	<b>Withdrawal period</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (3)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European	ml/ Bottle	100000110662/ 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			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (4)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European	ml/ Bag	100000110662/ 200000002166	
4.3.2.1.1	Strength (presentation single value)	European	200/1		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>4</b>	<b>Ingredient (5)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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			
4.3.2.2.1	Strength (concentration single value)	European			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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			
<b>4</b>	<b>Ingredient (6)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Water for injection	100000078023	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European	ml/ Bag	100000110662/ 200000002166	
4.3.2.1.1	Strength (presentation single value)	European	1000/1		
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>National</b>			
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	100000072175	
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>	1 <200000002111>	
5.3	Package identifier	European		PCKID-91001	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552151		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Bottle	200000002111	
5.6.2	Manufactured item quantity	European	200 <ml>	200 <100000110662>	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>National</b>			
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	100000072175	
5.1	Package description (NL)	National	Type II borosilicaat glazen flessen bevattende 400 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
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			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.5.1	Marketing authorisation number (package level)	National	BE-V1552152		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (3)</b>	<b>National</b>			
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	100000072175	
5.1	Package description (NL)	National	Type II borosilicaat glazen flessen bevattende 500 ml (volume 500 ml) diluent		
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bottle>	1 <200000002111>	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.3	Package identifier	European		PCKID-91003	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552153		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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		
<b>5</b>	<b>Packaged medicinal product (4)</b>	<b>National</b>			
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		



Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.1.1	Language	National	Dutch	100000072169	
5.2	Pack Size (structured values)	European	1 <bag>	1 <200000002166>	
5.3	Package identifier	European		PCKID-91004	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552154		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (5)</b>	<b>National</b>			
5.1	Package description (FR)	National	Sachets en chlorure de polyvinyle (PVC) contenant 400 ml		

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
			(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		PCKID-91005	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552155		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
5.7.1	Country	National	Belgium	100000000337	
5.7.2	Availability status	National	Not marketed	100000072074	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.7.3	Availability status date	National	20/10/2021		
<b>5</b>	<b>Packaged medicinal product (6)</b>	<b>National</b>			
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		PCKID-91006	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National	BE-V1552156		
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Bag	200000002166	
5.6.2	Manufactured item quantity	European	1000 <ml>	1000 <100000110662>	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
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

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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			
<b>1.8</b>	<b>Veterinary medicinal product name (1) - EU</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	Amoxicillin 150mg/ml maymo solution for injection		
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
1.8.2	Name Part	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>1.8</b>	<b>Veterinary medicinal product name (2) - FR</b>	<b>National</b>			
1.8.1	Veterinary medicinal product name	National	BIMOXYL LA 150 MG/ML SUSPENSION INJECTABLE POUR BOVINS OVINS ET PORCINS		
<b>1.8.3</b>	<b>Country/Language</b>	<b>National</b>			
1.8.3.1	Country	National	France	100000000395	
1.8.3.2	Language	National	French	100000072175	
1.8.2	Name Part	National			
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
					the UPD access policy
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			
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
<b>1.11</b>	<b>Attached Document (2) - FR</b>	<b>National</b>			
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		604332356524	Using system generated ID for CMS product
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European	BIMEDA ANIMAL HEALTH LIMITED	LOC-100019989	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information - FR</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	FR/V/10099234/2017		
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	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	IE/V/0362/001		
2.13.2	Procedure type	European	Decentralised procedure	100000155060	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	
<b>3.4</b>	<b>Withdrawal period (1)</b>	<b>European</b>			
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	
<b>3.4</b>	<b>Withdrawal period (3)</b>	<b>European</b>			
3.4.3	Note	European	Meat and offal: 21 days.		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
3.3	Target species (4)	European	Sheep	100000109022	
<b>3.4</b>	<b>Withdrawal period (4)</b>	<b>European</b>			
3.4.3	Note	European	Meat and offal: 21 days. Not authorised for use in sheep producing milk for human consumption.		
3.5	Administrable dose form	European	Pharmaceutical dose form not applicable	200000018781	For compatibility purpose with the FHIR API version R5#2
<b>4</b>	<b>Ingredient</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Amoxicillin trihydrate	100000092629	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European	amoxicillin	100000091596	
4.3.3.1.1	Reference strength (presentation)	European	mg / ml	100000110656/ 100000110662	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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			
<b>5</b>	<b>Packaged medicinal product (1)</b>	<b>European &amp; National</b>			
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			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Vial	200000002158	
5.6.2	Manufactured item quantity	European	100 <ml>	100 <100000110662>	

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
5.6.3	Manufactured dose form	European	Solution for injection	100000073863	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		
<b>5</b>	<b>Packaged medicinal product (2)</b>	<b>European</b>			
5.1	Package description - EU	European	Vial of 250 ml		
5.1.1	Language	European	English	100000072147	
5.1	Package description - FR	National	Boîte de 1 flacon de 250 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-45641	System generated
5.4	Legal status of supply	National			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (2)</b>	<b>European</b>			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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	
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
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		

## 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*



SPC 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
<b>1</b>	<b>Veterinary medicinal product</b>	<b>European</b>			
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

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
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	
<b>1.7</b>	<b>Product Classification</b>	<b>European</b>			
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			
<b>1.8</b>	<b>Veterinary medicinal product name (1) - EU</b>	<b>European</b>			
1.8.1	Veterinary medicinal product name	European	PLUSET 500 IU/500 IU powder and solvent for solution for injection		
<b>1.8.3</b>	<b>Country/Language</b>	<b>European</b>			
1.8.3.1	Country	European	EU	100000000390	
1.8.3.2	Language	European	English	100000072147	
1.8.2	Name Part	National			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>1.10</b>	<b>Pharmacovigilance Contact (QPPV)</b>	<b>European</b>			
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
<b>1.11</b>	<b>Attached Document (1) - EU</b>	<b>European</b>			
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	

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-it-v-0117-001-en.pdf		
1.11.9	(Attached document) related veterinary medicinal products	European		601236756723	Using system generated IDs for RMS & CMS products
<b>1.12</b>	<b>Product cross-reference</b>	<b>European &amp; National</b>			
1.12.1	Product cross-reference type	European & National			
1.12.2	Reference product Identifier	European & National			
1.12.3	Source product identifier	National			
<b>1.13</b>	<b>Manufacturing Business Operation</b>	<b>European</b>			
1.13.1	Manufacturer	European	Laboratorios Calier S.A.	LOC-100006613	
1.13.2	Manufacturing activity	European	Manufacturer responsible for batch certification	100000160407	
<b>2</b>	<b>Authorisation/registration/entitlement information - IT</b>	<b>European &amp; National</b>			
2.1	Authorisation/registration/entitlement type	European	Marketing authorisation	220000000061	
2.2	Authorisation/registration/entitlement number	National	AIC4567389		
2.3	Country	National	Italy	100000000430	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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	100000000337	
<b>2.13</b>	<b>Marketing authorisation procedure</b>	<b>European</b>			
2.13.1	Procedure number	European	IT/V/0117/001		
2.13.2	Procedure type	European	Mutual Recognition	100000155061	
<b>3</b>	<b>Pharmaceutical Product</b>	<b>European</b>			
<b>3.1</b>	<b>Ingredient</b>	<b>European</b>			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	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
3.3	Target species (1)	European	Cattle	100000108893	
<b>3.4</b>	<b>Withdrawal period (1)</b>	<b>European</b>			
3.4.3	Note	European	Cattle: meat and offal: Zero days milk: Zero hours		
<b>4</b>	<b>Ingredient (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Follicle-stimulating hormone	100000090586	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Luteinising hormone	100000124465	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European			
4.3.2.1.1	Strength (presentation single value)	European			

Vet EU IG Ref.	UPD data element name	European/National	Value	Value code	Note
4.3.2.2	Strength (concentration)	European	IU /ml	100000110671/ 100000110662	
4.3.2.2.1	Strength (concentration single value)	European	50/ 1		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>5</b>	<b>Packaged medicinal product</b>	<b>European &amp; National</b>			
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			
<b>5.5</b>	<b>Marketing authorisation (package level)</b>	<b>National</b>			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
5.5.1	Marketing authorisation number (package level)	National			
<b>5.6</b>	<b>Manufactured item (1)</b>	<b>European</b>			
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	
<b>4</b>	<b>Ingredient (1) - Manufactured item (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Follicle-stimulating hormone	100000090586	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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	



Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.2.2.1	Strength (concentration single value)	European	500/ 1		
<b>4</b>	<b>Ingredient (2) - Manufactured item (1)</b>	<b>European</b>			
4.1	Ingredient role	European	Active	100000072072	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Luteinising hormone	100000124465	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
4.3.3.1	Reference (Active) Substance	European			

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
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			
<b>5.6</b>	<b>Manufactured item (2)</b>	<b>European</b>			
5.6.1	Unit of presentation	European	Vial	20000002158	
5.6.2	Manufactured item quantity	European	21 <ml>	21 <100000110662>	
5.6.3	Manufactured dose form	European	Solvent for parenteral use	100000073881	
<b>4</b>	<b>Ingredient (1) - Manufactured item (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Excipient	100000072082	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	Chlorocresol	100000081847	

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
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		
<b>4</b>	<b>Ingredient (2)</b>	<b>European</b>			
4.1	Ingredient role	European	Excipient	100000072082	
<b>4.3</b>	<b>Substance</b>	<b>European</b>			
4.3.1	Substance	European	STERILE PYROGEN-FREE ISOTONIC NACL SOLUTE (0.9% W / V)	100000138946	
<b>4.3.2</b>	<b>Strength (quantitative composition)</b>	<b>European</b>			
4.3.2.1	Strength (presentation)	European	ml/ vial	100000110662/ 200000002158	
4.3.2.1.1	Strength (presentation single value)	European	21/ 1		

Vet EU IG Ref.	UPD data element name	European/ National	Value	Value code	Note
4.3.2.2	Strength (concentration)	European			
4.3.2.2.1	Strength (concentration single value)	European			
<b>4.3.3</b>	<b>Reference Strength</b>	<b>European</b>			
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			
<b>5.7</b>	<b>Availability status</b>	<b>National</b>			
5.7.1	Country	National	Italy	100000000430	
5.7.2	Availability status - IT	National	Not marketed	100000072074	
5.7.3	Availability status date - IT	National	30/06/2021		