



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 July 2021  
EMA/358889/2021  
Veterinary Medicines Division

## Overview of comments received on the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	Legemiddelverket, Norway
2	AnimalhealthEurope
3	Lægemiddelstyrelsen, Denmark
4	European Group for Generic Veterinary Products (EGGVP)
5	Läkemedelsverket, Sweden
6	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
7	Agence nationale du médicament vétérinaire, France
8	Agentur für Gesundheit und Ernährungssicherheit GmbH, Austria
9	European Medicines Agency
10	Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten, Belgium
11	Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Slovenia



## 1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	We think that there should be only one implementation guide both for UPD and PMS. This would increase readability of the documents, and better understanding that this is the same register.	While the UPD is also based on PMS as the data repository, there are some significant differences between the human and veterinary domain (e. g. in the relevant data fields). Therefore it was considered that separate implementation guides would provide more clarity on the requirements in each domain.
1	What will happen to the data in EUVETMED, will they be migrated to UPD by EMA?	As the data available in EUVETMDB is sourced from EudraPharm and is therefore neither complete nor of sufficient quality to fulfil the UPD requirements, the data will not be migrated.
3	Please be consistent in the use of the document title when referring to the Implementation Guide: "Chapter 4 of this document", "Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database", "Veterinary EU Implementation Guide (Vet EU IG) for the Union Product Database" We suggest that the short name should include all four identifying parts: "Vet" "EU" "UPD" and "Implementation Guide" / "IG" in order to clarify the scope and allow for easy identification of other possible VMP-Reg related implementation guides.	Change applied.
3	Chapter 6: practical examples is not included.	Chapter 6 will be published at the end of June 2021.
6	In a former version of Chapter 2 there was a chapter on volume of sales, where can this information be found now?	Details on the formats for the submission of certain data by MAHs are still under discussion and a new independent chapter on Volume of Sales will be created in due course.
6	Examples used are sometimes from the human domain, which should be avoided, e.g. line 503 SmPC.	Change applied throughout.

Stakeholder no.	General comment (if any)	Outcome (if applicable)
8	<p>We are missing a definition of a medicinal product which is a combination of name, strength and pharmaceutical form.</p> <p>We strongly recommend that the permanent identifier and the product identifier are stable as long as the product exists. In the document it is not so clear that this will be guaranteed. Any change in these identifiers will break synchronisation between databases.</p> <p>Do we correctly understand that the FHIR resource id provided by the UPD is the same as the permanent identifier for the medicinal product?</p>	<p>The name cannot be part of the identifier as it can change and is different in different countries. Yes the permanent ID and product ID are stable.</p> <p>About the FHIR resource id, yes the permanent identifier is the FHIR id for the medicinal product.</p>

## 2. Specific comments on text

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
<b>Introduction</b>			
Section 1	2	Can the MVP be defined here?	Section 1 has been reworded.
Section 2; Lines 105-107	3	Although it may not be clearly stated in the Regulation (EU) 2019/6, data in UPD on products authorised by the Commission must be entered by someone.	Centrally authorised products will be added into the UPD by EMA.
Section 2; Line 128	2	Submit 3 <sup>rd</sup> country product names by January 2022 - how is it achievable? MAH are very concerned that there will not be enough time between decisions on key issues (e.g., pack IDs.), upload of legacy data & provision of test environments and the deadline 28 Jan 22 for MAH to finalise systems, map and provide these data. These concerns have been raised in POG and VMP-Reg Stakeholder groups.	The concern is noted, the MVP will consider a simple solution for the provision of third country product names. It is understood that these can only be provided for products that have been submitted into the UPD.
Section 2; Line 130	2	It is not clear what is meant by 'any relevant additional data'. Does it mean data to complete any mandatory fields not uploaded at initial Legacy Data upload? Or perhaps non-mandatory data which becomes available in a variation application? Or even to provide all mandatory data for products where a MS fails to meet the deadline for uploading Legacy data?	Commission Implementing Regulation (EU) 2021/16 states that the NCAs should provide all information they have available. As some data might not be available for historical reasons, the requirements have been set as less prescriptive for legacy data.
Section 2; Lines 134-140	3	There must be an appropriate governance structure for any decisions about additional requirements for data beyond the requirements of the 'UPD minimum viable product' – in order to safeguard against undesirable "scope creep" during the future evolution of the UPD. The sentence starting "Such prioritisation should be defined..." does not specify by whom nor through which decision procedure.	The governance for future improvements of the UPD will be established in Q3/4 of 2021 as per Article 2(2) of Commission Implementing Regulation (EU) 2021/16.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
<b>Chapter 1</b>			
Section 2.1; Line 44	5	Industry: marketing authorisation holders, registration holders, product owners and applicants (further referred to as MAH), including relevant external service providers (e.g. consultants), and medicines developers;	Change applied.
Section 2.1; Line 59	4	Link to a page that no longer exists.	Corrected.
Section 2.2; Line 80	5	For the initial submission of veterinary authorised/registered medicinal products in UPD	Change applied.
Section 3; Lines 82-84	2	Process to be able to submit in UPD 'are described in the UPD registration guidance, to be published in 2021'. Participants are aware of ongoing discussion (and have expressed their concern about the limited time available to adapt to the eventual process and the associated systems availability), but readers will not be.	Concern noted; the registration guide will be published by summer 2021 and should clarify the situation.
Section 3; Lines 83-84	2	Why is the UPD registration guidance a separate document? How many documents will users have to read and understand?	Registration guidance is consulted by a user only once, while the implementation guide might need to be accessed more often. In line with other Agency systems, the registration guide will be a standalone document.
Section 3; Line 90	5	The detailed prerequisite steps and processes to be undertaken by NCAs and MAH	Change applied.
<b>Chapter 2</b>			
Table of Contents; Line 12	9	Please update Table of Contents.	Change applied.
Table of Contents; Line 12	9	Table of contents has not been refreshed and so numbering does not match the main body of the document. Please perform spellcheck.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Table of Contents; Line 43	6	Check table of content; in table of content: 2.10 = Ref. member state, in text (line 671) 2.10= destination wholesaler distributor and following sections	Corrected.
Glossary; Line 143	6	RUP is now SRP, please check for consistency throughout the document	Change applied.
Scope; Line 160	5	New abbreviation is agreed in CMDv (and included in the MS list; please change throughout document.	Change applied.
Scope; Line 163	5	To better reflect homeopathic and pet products	Change applied.
Scope; Line 173	7	Chapter 2 mainly focuses on authorised VMP and parallel trade products. Data fields requested for each type of products should be identified and clarified.	Examples will be published in the dedicated Chapter 6 at the end of June 2021.
Scope; Line 182	5	Clarify provisional data	Change applied.
Scope; Line 190	4	Paragraph not needed, these products are not VMPs so clearly not in scope	Section retained so it is clear what is not in scope.
Identification of a VMP; Line 196	5	It is important to describe the different levels of datasets as an introduction.	Change applied.
Identification of a VMP; Line 197	5	Would be good to be clearer	Change applied.
Identification of a VMP; Line 207	5	Text less clear in this context	Text amended.
Identification of a VMP; Line 212	5	To be very clear, include Product in the heading	Rejected. Title already contains "product" and not considered clearer mentioning it a 2nd time.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Identification of a VMP; Lines 215-225	6	How can a unique identifier be used for veterinary medicinal products across Member States, which have undergone harmonisation (this might be possible only for harmonised SPCs according to Article 70 of EU Regulation 2019/6 from the same MAH) of their SPCs, if the initial regulatory procedure number is a defining character for the product identifier? Multiple products, which will get harmonised with each other in the future, will still have differing initial regulatory procedure numbers. Please clarify	Issue under investigation.
Identification of a VMP; Line 220	5	To be very clear, include Product ID	Rejected, as not considered to make the sentence clearer.
Identification of a VMP; Line 222	8	Not only in the case of transfer of ownership but also in the case of a RMS transfer.	Change applied.
Identification of a VMP; Line 225	8	Please confirm that the UPD level 1 identifier does not change in case of a changed procedure number (e.g. RMS transfer or corrections).	This is confirmed.
Identification of a VMP; Line 225	5	It is not of any use to have the full procedure number here, i.e. if it was a DCP, MRP or a RUP/SRP that was the first procedure, since they all end up in having one MRP product that will have that core number to be used for subsequent variations regardless the start.	Change applied.
Identification of a VMP; Line 228	8	Footnote 3 is not clear in this context due to mentioning the permanent ID.	Change applied.
Identification of a VMP; Line 228	5	Footnote 4: Better to use the wording manufactured item in this footnote, since we don't use the pharmaceutical product concept in UPD	Change applied.
Identification of a VMP; Line 231	5	Add a first bullet point to clarify that the IOD is stable as below.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Identification of a VMP; Lines 231-252	5	The version control is very strange for a "stable" ID. It needs to be better described, e.g. that the complete product dataset will be given different versions during the lifecycle, but the ID will still stay the same (be stable).	This is correct, we have reviewed the text on versioning, which is in fact described in the SPOR API or more general user documentation.
Identification of a VMP; Line 231-235	3	It seems to us that a phrase like "the same Product ID" is sometimes used to refer to the entire entity/data set identified by the "Product ID" rather than to the data element "Product ID". E.g. in the text of lines 231-235, it is not clear what the exact meaning of the following is: "... will generate a new version of the Product ID...". If the identifier, the Product ID, is the same, what does a new version imply? Please be very explicit in the text concerning the intended meaning of words like "ID" and "product".	Change applied throughout document.
Identification of a VMP; Line 236	8	Sometimes a MAH wants to have a separate Marketing Authorisation for a new target species that is added in the lifecycle. The decision to include the new target species in the same MA or obtain a new one lies with the MAH. So this should not be an automatism in the system. The Competent Authority should have somewhat of a control whether a new product is created in the UPD or not.	When this case will happen with a specific case in the future, we suggest to bring for discussion to CMDv. In general, it should be a separate MA, so new procedure number. Ultimately this is a business decision.
Identification of a VMP; Line 240	8	This paragraph is confusing because it mentions attributes (e.g. name) which are not characteristics of level 1.	This is to clarify that the product ID is stable, it's the versioning that is changing throughout the lifecycle of a product data entry. This is also addressing the concern raised in comment asking whether the ID would be stable.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Identification of a VMP; Line 253	1	Level 2 Permanent identifier: Is Permanent identifier the same as PMS ID? Proposed change (if any): Align with IG for human use	Change applied.
Identification of a VMP; Line 253	8	We propose to clearly state that this permanent identifier is the unique identifier to clearly identify a definite medicinal product in the UPD. We also think that the naming convention is confusing between level 1 and level 2.	It is a unique identifier of the veterinary medicinal product in the Union product database. The naming convention is based on the Commission Implementing Regulation (EU) 2021/16.
Identification of a VMP; Line 255	5	Please add text Listed in Domain (RMS List ID 100000000004); only the term given above to be used	Change applied.
Identification of a VMP; Line 257	5	Change/add text for clarification [...] authorised in several Member States from the same MRP/DCP or SRP are separately identified [...]	Change applied.
Identification of a VMP; Line 261	5	Proposed change (if any): Add (level 1) for clarification in the bullet point - Product ID (level 1)	Change applied.
Identification of a VMP; Line 263	8	MAH cannot be a characteristic because it would make identifier unstable.	If there is a change of MAH, the permanent identifier will not change, but the versioning will (clarified in second bullet after characteristics).
Identification of a VMP; Line 273	8	Technically we do not understand what a "new version" of a permanent identifier means and how this will be technically realised. Versioning of permanent identifiers will increase the technical effort and is in principle the same as you would define a new identifier. We recommend that the permanent identifier will not change during the lifecycle of the product.	Corresponding text changed in order to reflect that the versioning applies to the product and not to its identifier.
Identification of a VMP; Line 273	5	Again, the version control is very confusion and not clearly described. Would propose to delete some text	This is correct, we have reviewed the text on versioning, which is in fact also described in the SPOR API or more general user documentation.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Identification of a VMP; Line 282	5	We assume the identifiers themselves would not be versioned. The products will be versioned, and the identifiers will have a version identifier to supplement the product identifiers. Proposed change (if any): To replace the last sentence with: Both the Product ID (level 1) and the Permanent ID (level 2) will be supplemented with version identifiers to uniquely identify a particular version of a product.	Corresponding text changed in order to reflect that the versioning applies to the product and not to its identifier.
Identification of a VMP; Line 283	8	Identifiers should not have a versioning. Do you mean a versioning of the data behind the identifiers?	Corresponding text changed in order to reflect that the versioning applies to the product and not to its identifier.
Identification of a VMP; Lines 287-288	3	The wording of the text favours a reading where the EEA is seen as one unit. Is it not the case that each EEA country must submit a national data set and each get a (different) Permanent Identifier assigned?	Clarification provided.
Identification of a VMP; Line 288	5	Add some text for clarification [...] assigned with a dedicated EEA Permanent Identifier (level 2) for each country. This will result in a total of four Permanent ID (level 2) for CAPs, one for the EU and one each for NO, IS and LI.	Change applied.
Identification of a VMP; Line 289	7	In the figure representing the UPD IDs, the second product ID 790 authorised in the country 2 shall have the same pack sizes than those authorised in the common dataset and product 1. Pack sizes authorised are common but the availability on the market could be different between member states.	Confirmed.
Identification of a VMP; Line 289	8	Packages are part of a common data set in MRP/DCP and will be further described in the national data e.g. translated package description. The diagram needs to be adapted.	The diagram has been updated accordingly, and all packages are now represented on each of the products under their national dataset.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Identification of a VMP; Line 290	2	Figure 1 on UPD Product Identifiers should depict the situation of Product IDs and Permanent IDs per procedure type. It is AnimalhealthEurope's understanding of the following: <ul style="list-style-type: none"> <li>- CAPs: 1 Product ID + 4 Permanent IDs (EU, IC, LI, NO)</li> <li>- NAPs in an MRP/DCP/RUP: 1 Product ID + n Permanent IDs (n = number of MS involved as either RMS or CMS)</li> <li>- NAPs authorized by NP: 1 Product ID + 1 Permanent ID per country</li> </ul>	Change applied.
User Guide; Lines 304-305	5	Add some word in both lines: [...] electronic submission of veterinary medicinal product data and documents into the UPD	Change applied.
User guide; Line 308	5	Please, add the below text: The FHIR message is based on the IDMP standards for human medicines with suitable modifications for veterinary products and the UPD.	Change applied.
User guide; Line 310	7	In the description of the requirement "Repeatable", an explanation on the class could be useful: "A class could be repeatable with repeatable or not individual data fields. A complete set of data fields is repeated in this case"	Change applied.
User guide; Line 310	7	In the description of the requirement "Conformance", an explanation on the class could be useful: "a class could be conditional and data fields belonging to the class could be mandatory. Once the conditions for the class are fulfilled, all mandatory data fields shall be fulfilled. If the conditions are not fulfilled, none of the data fields belonging to the class shall be provided".	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
User guide; Line 310	7	Tags related to ISO IDMP "ISO element name" and "ISO path" are not relevant for the veterinary domain, as the ISO IDMP is not applicable to VMPs. We propose to delete the 2 lines. ISO Element Name - Any mapping to ISO IDMP standards Note: for the implementation of the UPD it is not required to implement the ISO IDMP standards. ISO Path- The mapping of the ISO IDMP technical specifications.	Since we have no requirement to align with ISO we have just retained in the documentation the mapping to the FHIR path which is now in line with the IG for human use.
User guide; Line 310	9	The links to "FHIR resource" list are to R5 Preview 3. I was expecting this to be linked to R5 Preview 2.	Change applied.
User guide; Line 310	5	Clarify in the introduction FHIR/IDMP as proposed for line 308 and then delete here. Proposed change (if any): Please, delete text as below: And mapping to ISO IDMP standards Note: for the implementation of the UPD it is not required to implement the ISO IDMP standards.	Change applied.
User Guide; Lines 316-317	2	"Terms in RMS shall be accepted with any status, unless specified otherwise." Comment: this statement is supported, since the go live of the UPD should not block in any way regulatory processes.	We are referring to creation of VMP, so status of terms should be current, unless specified otherwise.
User guide; Line 317	7	Terms in RMS shall only be accepted under CURRENT status for the creation of new products. "Terms in RMS shall be accepted with any CURRENT status, unless specified otherwise"	Change applied.
User guide; Line 317	5	Add information about new RMS terms as needed. If needed, new terms can be requested via the SPOR portal.	Change applied.
User guide; Line 318	8	Is the selection from OMS mandatory in the future?	This is confirmed.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
User guide; Line 325	5	Add info about how to request. [...] is not yet available in OMS, the details must first be registered in OMS via the SPOR portal [...]	Change applied.
User guide; Line 326	9	A UPD user will be able, when creating or updating a product, to select 'active' and 'inactive' organisations from OMS. The guide should reflect that.	Change applied.
User Guide; Lines 331-333	6	Why will the data elements be suppressed silently? Will the user not get any warning message?	In the IT solution implementation, because they are not applicable, they will not be taken into account.
User guide; Line 337	9	Link is to R5 Preview 3 and expected this to be link to R5 Preview 2.	Change applied.
User guide; Line 338	1	Figure 2 on page 12: The pharmaceutical product is missing in the conceptual data model, between Medicinal Product and Ingredient.  Proposed change (if any): Add the class for Pharmaceutical Product	Change applied.
User guide; Line 338	7	The UPD conceptual data model should be updated to reflect the update of the VET EU IG.	The conceptual data model does not model all the physical resources and is just illustrative.
User guide; Line 343	9	Is it correct that this IG aligns to R5 Preview 3 when actual implementation is R5 Preview 2?	Change applied.
User Guide; Lines 343-347	5	Concerning the link, 'Release 5 Preview #3'. it is not to the relevant part of the FHIR standard, but rather to a general FHIR release 5 page. It should link specifically to the part of the FHIR standard that the UPD will use. (Also the text in line 347 needs to be updated in the next version.)	We will modify the version of the FHIR specifications that the next implementation of UPD will support. The SPOR API v2 specification makes explicit reference to the individual FHIR resources.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
User guide; Line 348	5	Please add the text in brackets: <a href="http://build.fhir.org/resourcelist.html">http://build.fhir.org/resourcelist.html</a> Add: (section Medication Definition)	Change applied.
Section 1; Line 350	7	Add a data field "Product category" from the RMS list Product category to identify chemical, immunological and homeopathic products to be able to deal with conditional conformance of some data fields.	This will be done based on legal basis for homeopathics, for chemicals and immunologicals, there is no specific requirement to identify them in the MVP.
Section 1.2; Line 359	3	The section 1.2. Product Status is more about the status of the database record in UPD than about the product.	Product Status has been renamed to "Product Record Status" in the Vet EU IG.
Section 1.2; Line 359	5	Listed in Record Status (RMS List ID 200000005003); only terms listed above to be used	Change applied.
Section 1.2; Line 362	7	Product status: describe the impact of any change of the authorisation status on the product status. <ul style="list-style-type: none"> <li>· Provisional: initial product state applicable to products approved under DCP/MRP/RUP procedure, but not yet authorised in each individual Member State. The "PROVISIONAL" product status is linked to the authorisation status "PENDING"</li> <li>· Current: Initial status for the following products when they are submitted to the UPD: CAP, NAP, registered homeopathic products, products allowed to be used in a member State in accordance with Article 5(6) of Regulation (EU) 2019/6 and parallel traded products. The product status "CURRENT" remains if the authorisation status change to "valid", or "suspended"</li> <li>· Non-current : status applicable to any product with an authorisation status changed to "revoked" or "withdrawn"</li> <li>· Nullified: status applicable to any product that is deleted by a user</li> </ul>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.2; Lines 362-363	6	Please specify 'non-current' in the user guidance box	Change applied.
Section 1.2; Line 362	6	Provisional status: Does this mean that DCP/MRP/RUP products will stay in the provisional status, as long as an authorization procedure in single countries is still ongoing? At which state data will be published?	The definition of 'Provisional': initial product status applicable to a product approved under MRP/DCP/SRP procedure but not yet authorised in a relevant member state.
Section 1.2; Line 364	7	Add the example NON-CURRENT: Provisional (200000005005), Current (200000005004), Non-Current (200000005006), Nullified (200000005007)	Change applied.
Section 1.3; Line 365	1	The ISO path for Authorized pharmaceutical form is given as: /MedicinalProduct/CombinedPharmaceuticalDoseForm This is not in line with the IG for human use where an attribute named AuthorisedPharmaceuticalDoseForm is added at the level of a Medicinal Product. Proposed change (if any): Align with IG for human use	Since we have no requirement to align with ISO we have just retained in the documentation the mapping to the FHIR path which is now in line with the IG for human use.
Section 1.3; Line 365	7	The pharmaceutical form of the VMP should be aligned to one of the lists mentioned but not all lists for the mapping of already authorised products. This has to be updated in the Chapter 4 for legacy data. Maybe this has to be mentioned in the table : either the "Pharmaceutical dose form" or "Combined pharmaceutical dose form" or "Combined term" or "Combined Package". The excel table provided to the change liaison listing data fields, is not up to date for this point (all lists are mandatory) and needs an update.	Change applied.  The document provided to vet change liaisons what a draft snapshot of the situation at the time, please refer only to the overview provided in Chapter 4 as published.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.3; Line 365	9	MedicinalProductDefinition.combinedPharmaceuticalDoseForm Not repeatable although there is a business need to have that attribute repeatable. In the H domain they have a different mapping for it.	Change applied.
Section 1.3; Line 365	9	Proposal to use FHIR extension which allows for multiple values.	Change applied.
Section 1.3; Line 371	8	As already mentioned in a discussion between CMDv and EDQM: We have a product with 2 pharmaceutical forms: Mitex Ear drops and cutaneous suspension for dogs and cats. We applied for a combined term at EDQM but it was refused. What to do in the UPD in such a case?	The term could be created as non-current in RMS and will not have EDQM ID.
Section 1.4; Line 373	6	In User Guidance second to last line: ...(see section 5.4...) please change to "Section 6.4"	Change applied.
Section 1.4; Line 373	7	Comment: the legal status for the supply is not repeatable. However, it should be repeatable for MRP/DCP/SRP/NAP. Proposed change (if any): "yes" to repeatable.	The legal status of supply is a national dataset, so will be specified per country. No need to have it repeatable as a field, because each of the MS will provide its own legal status of supply.
Section 1.4; Line 373	9	Section reference to 5.4 is not correct in "User Guidance"	Change applied.
Section 1.4; Line 373	9	Contradictory statements. Says if at package level to be blank at product level. Then this has been added in red "The term Veterinary medicinal product subject to veterinary prescription except for some pack sizes will then be shown at the product level."	Change applied.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.4; Line 373	5	<p>Please add text</p> <p>The legal status of supply is usually defined at UPD product level 2 and should be specified as Veterinary Medicinal product not subject to veterinary prescription or Veterinary medicinal product subject to veterinary prescription.</p> <p>And also add text at the end for clarification: The term Veterinary medicinal product subject to veterinary prescription except for some pack sizes will then be shown at the product level.</p> <p>Further detailed status of supply could be relevant in future versions of the UPD.</p>	Change applied.
Section 1.4; Line 373	9	Legal status of supply' to be changed for 'Legal status for the supply' based on UPD Implementing Act, RMS list, etc.	Change applied.
Section 1.4; Line 373	9	<p>MedicinalProductDefinition.legalStatusOfSupply</p> <p>Can it be different per country for CAP?</p>	Change applied.
Section 1.5; Line 377	5	<p>Probably it would not be possible to report on "a group of countries", so please delete.</p> <p>Proposed change (if any): Delete: ...or a group of countries (in two places in the text)</p>	Change applied.
Section 1.5; Line 377	5	<p>"The term "No Data Provided" should always be set when the product is created in the UPD, since this information is at that time not yet provided by the MAH. This would also be the case for the products uploaded as the initial input to the UPD where the MAH also needs to add this data for each product.</p> <p><del>Since this information is to be provided by the MAH, at the creation of the veterinary medicinal product by the NCAs, this information is not known yet, so the availability status shall be specified with the value "No Data Provided".</del></p>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.5; Line 377	5	Change the term given: date for " <del>not marketed</del> No data provided")	Change applied.
Section 1.5; Line 377	9	I understand that it has been decided that Availability status will be at Package level and not product level. Therefore, this section will be moved to be within section 6 Packaged medicinal product	Change applied.
Section 1.5; Line 384	6	How is it controlled that the MAH fills in data in this field? It is mandatory but is there a red flag if not changed by MAH from "No Data Provided" to "marketed"?	Not relevant for drafting of the EU IG - process will be in place for completion of the data by MAH.
Section 1.5; Lines 384-386	5	Similar information is given in the Tag User guidance of 1.5.2. Availability status (see comment also for line 390 below) and would be better to stay only there and be deleted in the introduction. Proposed change (if any): Delete the following text: Since this information is to be provided by the MAH, at the creation of the veterinary medicinal product following initial marketing authorisation approval by the NCAs, this information is not known yet, so the availability status shall be specified with the value "No Data Provided".	Change applied.
Section 1.5; Lines 386 and 390	2	The term 'No Data Provided' was intended for use in legacy data for products authorised before Jan 22. Such products may be, or may not be, marketed. As the case refers to the creation of a new product by CA after application but before authorisation it follows that it cannot legally be on the market. Therefore 'Not Marketed' is more appropriate.	The sentence "It is also the default term when a new product is created." has been added in the description of the term "not marketed" and the "no data provided" has been removed.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.5.1; Line 387	7	The Availability status class is repeatable, but the data field Country should not be repeatable. All the class is repeatable, at each time country, availability status and availability state date together. - repeatable for 1.5.1 Country No	Change applied.
Section 1.5.1; Line 387	9	Repeatable should be No. Only 1 country can be included within each marketingStatus entry in FHIR. See <a href="http://hl7.org/fhir/2020May/marketingstatus.html#MarketingStatus">http://hl7.org/fhir/2020May/marketingstatus.html#MarketingStatus</a>	Change applied.
Section 1.5.1; Line 387	2	Need a value "Non-EEA country" for sales data reporting.	SPOR team informed
Section 1.5.1; Line 387	5	Propose to use national dataset instead of national entitlement everywhere in the document, since it is easier to understand. Proposed change (if any): the national <del>entitlement</del> dataset	Change applied.
Section 1.5.1; Line 389	2	Will the term name or the short name will be used?	Change applied (short name to be used).
Section 1.5.2; Line 390	6	Will the time period for the term "temporarily unavailable" be clearly defined anywhere? When exactly will MAHs be required to change the status to "temporarily unavailable"? Proposed change (if any): Please clarify what is meant here to avoid confusion. In the table it says: "The term "temporarily unavailable" should be specified as a disruption of supply from the MAH which would lead to an extended disruption in supply to the retailers for a long period of time (e.g. for instance more than 3 months). In EU Regulation 2019/6 a period is not specified.	This is not defined legally for the time being.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.5.2; Line 390	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.
Section 1.5.3; Lines 394-395	6	Table under 1.5.3 “...the availability status date is mandatory to be provided.” Includes this sentence that an entry cannot be finished without entering the actual date? How will be guaranteed that the entries by the MAH as asked for in 2019/6 Art. 55 2. (a) (vii) will be up-to-date and changes will be entered in a timely manner?	The information provided by the MAHs to the UPD related to the availability status will be validated against the rules defined in the Vet EU IG, therefore any submission that does not contain the corresponding dates will be automatically rejected.  Regarding the control of whether the information has been submitted in a timely manner, UPD cannot control that. Having correct and up to date information in the database is the responsibility of the MAH (Article 18.8 of Commission Implementing Regulation (EU) 2021/16).
Section 1.5.3; Line 394	6	Table under 1.5.3 Availability status date “...The first value will be created by the system, at the time of initial entry of the product into the UPD (date for “not marketed”). ...” But in lines 384 to 386 is says “Since this information is to be provided by the MAH, at the creation of the veterinary medicinal product following initial marketing authorisation approval by the NCAs, this information is not known yet, so the availability status shall be specified with the value “No Data Provided”. Thus, it sounds as if the first entry will be done by NCAs or the Agency, respectively.	"No data provided" needs to be provided as a default value.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.6; Line 396	5	Minor update of text The product classification class describes a set of classifications (regulatory and non-regulatory) which applies to the veterinary medicinal product, defined in the UPD by legal basis and ATC code.	Change applied.
Section 1.6.1; Line 398	6	Changes proposed: please add another common example: Full application - known active substance (Article 8 of Regulation (EU) 2019/6) Please delete example generic with old legal basis ((Art. 13 (1) 2001/82/EC	Change applied.
Section 1.6.1; Line 398	7	Legal basis: as described, legal basis are only described for authorised medicinal product, the conformance is conditional to the regulatory entitlement type. Conformance: Conditional	Change applied.
Section 1.6.1; Line 398	7	The legal basis can evolve during the lifecycle of specific products. For instance for limited markets and exceptional circumstances when they will be transferred to a complete dossier. The business process is under discussion at CMDv level for limited market.	Noted.
Section 1.6.1; Line 398	9	List name is "Marketing Authorisation Application Legal Basis" (in PROD). In lower environments the list name is "Application legal basis" and they don't contain the new values for UPD. Are you liaising with SPOR to align the name and terms in RMS - in all environments (Dev, SIT, UAT & PROD)?	List and term names aligned between SPOR and IG; all terms available in all environments.
Section 1.6.1; Line 398	9	RegulatedAuthorization.basis  Can we not move this to the definition of the RegulatedAuthorization instead of the generic product classification?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.6.2; Line 402	6	Please verify FHIR Element and Path	The FHIR Path for ATC Vet Code of MedicinalProductDefinition.productClassification is correct. FHIR Element Name corrected.
Section 1.6.2; Line 402	7	1.6.2. ATC Vet Code is not requested for homeopathic products authorised or registered. The condition shall refer to the product category "Homeopathic Medicinal Product" 100000155549 · ATC vet code is not applicable for Authorised and Registered veterinary homeopathic medicinal products.	Change applied.
Section 1.6.2; Line 402	9	If product is not "Registered veterinary homeopathic medicinal product" is it mandatory to have either a code specified or 1.6.3 ATC Vet Code flag set?	Change applied.
Section 1.6.2; Line 402	5	Concerning the text: "The ATC Code is not applicable to Registered veterinary homeopathic medicinal products, should the value for this veterinary medicinal product be specified, the value must be set to 'False'." - Who would set this flag? Could it be set automatically to 'false' for this product type?	Change applied.
Section 1.6.2; Line 402	9	Vet EU IG: "If ATCvet code is not available because not yet assigned by the ATCvet Code list maintenance organisation and not yet available in RMS, the field should be left empty but information on its unavailability must be provided in the ATC Vet Code flag (i.e. at least one of ATC vet code OR the ATC Vet Code flag must be provided if applicable)." Is it possible an scenario where the product has 3 ATC Vet codes and two of them are pending? In this case the user will have 2 pending flags and 1 correct ATC Vet Code. To confirm if it is possible.	Clarification provided.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.6.3; Line 406	1	ATCcodeFlag, is this flag part of the PMS, so it may be used for medicinal products for human use as well? Proposed change (if any): Align with IG for human use	No change. ATCvet code flag only applies to veterinary medicines.
Section 1.6.3; Line 406	6	This flag should be set and maintained in RMS. This field should not be defined by the user but automatically be retrieved and updated from RMS.	Not an RMS term, this field is Boolean, i.e. Yes or No value.
Section 1.6.3; Line 406	8	An average user will not understand what is meant by a data field called "ATC vet code flag" with a value of true or false. Will there be an info button in the UI or different labels.	It is described in the EU Vet IG and a tooltip could be added.
Section 1.6.3; Line 406	9	The FHIR path should be MedicinalProductDefinition.productClassification.extension.atcPending	Change applied.
Section 1.7; Line 415	5	Add text for clarification [...] be set for each product in each country and must also be repeated as per applicable languages in [...]	Change applied.
Section 1.7; Line 418	5	Add text for clarification name in English as used in the procedure	Change applied.
Section 1.7; Line 429	6	Information should be given if inclusion of any additional veterinary medicinal product name as applicable to third countries by the MAH is mandatory or optional.	This is a procedural business process to be established - cannot be mandated technically.
Section 1.7; Line 429	5	Add text for clarification (as assumed) These alternative product names would not be visible to the public in the UPD but would only appear in the MAH and CA UI and, most important, in the Pharmacovigilance database.	Rejected - visibility of the fields should be described in the access policy document.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.7; Lines 429-430	2	It should be clarified in which characters and language additional veterinary medicinal product names as applicable to third countries shall be specified. Would Cyrillic or Japanese characters be acceptable, or should it be Latin characters? Should it be the veterinary medicinal product name in local language (and possibly Latin characters) or the English translation?	Change applied.
Section 1.7; Lines 429-430	2	Confirmation is sought that additional veterinary medicinal product names as applicable to third countries shall not be specified at country/language level, since entered as alternative names within the common/European dataset. In case of products approved in multiple EU/EEA Member States per national procedure, the third countries product names should not be requested multiple times.	Comment noted.
Section 1.7; Lines 429-430	2	It is assumed the veterinary medicinal product names as applicable to third countries will not be part of the information accessible to the general public.	Confirmed, to be clarified in Access Policy.
Section 1.7.1; Line 432	1	In the Tag User Guidance: "The full veterinary medicinal product name (invented name, strength, pharmaceutical form)," missing "Dose" as in pharmaceutical dose form? Proposed change (if any): Add "dose" to the text.	Change applied.
Section 1.7.1; Line 432	6	Values: Special characters: it might need to exclude the special character "trade mark" which is not allowed to use in VMP name.	Change applied.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.7.1; Line 432	2	For products approved by MRP/DCP/RUP, and in case English is an official language in none of the Member States involved in the procedure, will the product name as expressed in the application form and common English SPC entered by the RMS as part of the common/European data set remain visible to the general public once all Member States have entered their national data set? We believe this would be helpful to the general public.	Change applied.
Section 1.7.2; Line 435	6	'ID' should be written in capital letters. Furthermore, if only the value '220000000001' as ID for the term 'Full name' shall be included in the section '1.7.2 Type' , could it be set by default?	Rejected, because other options are applicable for CAPs.
Section 1.7.2; Line 435	9	New details regarding vaccine name for CAP - does this mean populate FULL NAME plus a Name Part for Scientific; or just one name in fullname with scientific name type term ID. As Value says must use full name type. Only affects EMA	Change applied.
Section 1.7.2; Line 435	9	The guide needs to specify that for vaccines the scientific name part will need to be provide, so for this name the user will need to provide the RMS term Id 220000000003	Change applied.
Section 1.7.3; Line 436	9	Clarification needs to be added to the guide related to how the country and language will be captured for CAP products.	Change applied.
Section 1.7.3; Lines 439-441	3	As stated, the data structure that is repeatable is the medicinal product name class. Thus, the final sentence in this paragraph is misleading.	Change applied.
Section 1.7.3; Line 440	9	It is not country/language class that should be repeated, but the entire "name" class.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.7.3.1; Line 443	8	Why do the CMSs have to choose the country? For MRP/DCP products the RMS creates the products at End of Procedure for all CMSs, doesn't it? So the country is already there	No, the CMSs have to create their own national datasets, and add their national translations with the applicable country. RMS will only provide the product name in English.
Section 1.7.3.1; Line 443	9	Values - Is any validation to be applied if the value is not selected from the RMS Country list? Is any reference to any other list to be accepted?	Change applied.
Section 1.7.3.1; Line 443	9	Clarification needed: what is expected in country for CAPs products? Are we expecting the name in 24 languages? Can we provide examples please for CAPs? Is the country for the EN name 'EU' or a country where EN is the mother language?	Change applied.
Section 1.7.3.2; Line 446	9	Section numbers for 1.7.3.1 and 1.7.3.2 need to be corrected as parent section is now 1.6.3	Change applied.
Section 1.8; Line 449	7	A link between the PSMF and the MAH will be appreciated.	This is achieved with the location ID in OMS, if the PSMF is kept at the premises of the MAH.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.8; Lines 449, 457-461 462, 463, 464, 466, 469, 472, 473	5	<p>Delete most of the text in the last bullet point to keep it clear (as assumed to be meant)</p> <p>The unique pharmacovigilance master file location information should be submitted to the database as follows:</p> <ol style="list-style-type: none"> <li>1) The PSMF reference number (code) as assigned by the QPPV.</li> <li>2) The PSMF location stated as a LOC ID linked to an organisation listed in OMS. Change the headings a bit to make it in line with normally used wordings/abbreviations. IDMP terms are not important to keep strict in the headings for the vet IG. Propose to Change the Headings to:</li> </ol> <p>(Pharmacovigilance System) Master file  (PSMF) File type  (PSMF) File code  (PSMF) File location  Pharmacovigilance Contact (QPPV)  (QPPV) Identifier  (QPPV) Location</p>	Change applied.
Section 1.8; Line 449	9	<p>Constitutes mandatory attribute according to FHIR.</p> <p>DocumentReference.status  DocumentReference.content  DocumentReference.content.attachment  and  This is the mapping for 1.8.3 (PSM) File location  DocumentReference.custodian</p>	FHIR paths were reviewed in order to align veterinary and human domains to map PSMF

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.8; Lines 457 and 465	6	<p>PSMF location reference number</p> <p>What is the PSMF location reference number. It is not PSMF reference number? It should be really clarified that the PSMF location reference number is not the PSMF reference number coded below under 1.8.2. (PSM) File code</p> <p>Another question:</p> <p>It is stated in (1) At the time of the marketing authorisation application, the applicant should submit electronically the PSMF location reference number (...). Is this meant as an entry in the eAF? Or a separate entry in a field in the UPD additional to the eAF? Or could this be stated on a document uploaded with the dossier via CESP for example? This would also be an electronic submission.</p> <p>If this location is a new one, then the OMS entry has to be amended/updated first before this PSMF location reference number can be generated and entered?</p>	Clarification provided.
Section 1.8.2; Lines 463-464	6	Value: string....a free text insertion may by error prone, perhaps a standardised format might be better.	Rejected.
Section 1.8.3; Line 465	9	Table is not complete and has no FHIR path	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.8ff.; Lines 465ff.	6	<p>Comment to 1.8 and 1.9: Additional PSMF data and QPPV (Summary of the PSMF)</p> <p>The Summary of the PSMF contains information about the record management system and may more data (depending final version of respective Implementing Regulation). There should be a possibility to include these data and in case of changes (VNRA) occur this must be updated in the UPD.</p> <p>Proposed change (if any): Therefore, fields are needed all information from PSMF Summary. E.g. for the record management system a field where the "name of the database used" can be entered, e.g. as a RMS list entry(?) or the type of system at least (e.g. database, Excel, MS Office, etc.) and in case of a commercial database a second field for the name of the database (as string value or codable via RMS list).</p> <p>1.9. Contact (QPPV) -&gt; related topic: Changes in the Summary of PSMF</p> <p>Proposed change (if any): Add a field to load up the "statement" between QPPV and MAH as is asked for in the "Summary of the PSMF" and should therefore be able to be updated in the UPD for notification when changes in the summary of the PSMF occur.</p>	Information within PSMF (incl. PSMF summary) are not recorded in UPD. Any such changes must be managed elsewhere.
Section 1.9; Line 466	6	<p>Comment: The required data here is very sparse. Will more data fields be added here (i.e. contact information, what about email/ phone/fax/ mobile contact data)? We have manual effort to provide the required data and a finalisation of the required information is necessary before we can perform this work.</p> <p>For our understanding these will be the information that will be used in case of trying to contact the QPPV.</p>	Contact information is not in MVP (legally required fields from Commission Implementing Regulation (EU) 2021/16); can be considered/discussed for prioritisation in post-MVP improvements.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.9; Line 466	9	In the semantic we would also need a mapping to a Practitioner and we only have a mapping to PractitionerRole, check with H domain.	FHIR paths were reviewed in order to align veterinary and human domains to map PSMF
Section 1.9.1; Line 469	6	Please verify FHIR Path (brackets)	Change applied. The resource name between parentheses represents the type that is being referenced from the attribute.
Section 1.9.1; Line 469	9	Similar to previous comment, style of how reference is made from one Resource to another. Decide on the one style and apply consistently to all attributes like this.	Change applied.
Section 1.9.3; Line 473	6	Please specify FHIR information.	Change applied.
Section 1.9.3; Line 473	9	Table is not complete and has no FHIR path	Change applied.
Section 1.9.3; Line 473	6	Contact details, are these only postal address and country? What about email/ phone/fax/ mobile contact data? These would be probably the ones that will be used in case of trying to contact the QPPV.	Contact information is not in minimum viable product for the UPD (refer to Commission Implementing Regulation (EU) 2021/16). This can be considered/discussed for prioritisation in post-MVP improvements.
Section 1.10; Line 474	7	There is no "general" table here mentioning information as for other data. It should be added to clarify if the attached documents are repeatable, mandatory, etc.	Change applied.
Section 1.10; Line 474	8	Is it also possible not to have any product information text for Art. 5(6) products? I'm not sure that we will have a text for such products (the handling of such products has to be specified in the AT law and this hasn't been done yet).	The requirements for Article 5(6) products will be discussed at a later stage, as including those in the UPD is only mandatory from 2024.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.10; Lines 474ff.	3	The description prescribes both submission of the identifier "1.10.1. (Attached document) identifier (master)" ("The ID assigned to the document once it is uploaded to the UPD system") and of the document itself "1.10.6. (Attached document) content" as part of the FHIR payload.	Change applied.
Section 1.10; Lines 474ff.	3	It would seem that the data model lacks an element for information about the Country for the Attached document. For CAPs, the current model does not seem to allow for a distinction between e.g. SPC in German language for Germany and SPC in German Language for Austria.	Change applied.
Section 1.10; Line 475	5	Important to state it is the public version of the AR	Change applied.
Section 1.10; Lines 477-481	2	For products approved by MRP/DCP/RUP, and in case English is an official language in none of the Member States involved in the procedure, will the English version of the product information (SPC/PL/LAB) agreed at the end of the procedure attached by the RMS as part of the common/European data set remain visible to the general public once all Member States have entered their national translations? We believe this would be helpful to the general public.	Data publication is out of scope of this guidance.
Section 1.10.1; Line 493	9	User Guidance - "The ID assigned to the document once it is uploaded to the UPD system must be specified. " This statement conflicts with Values row where it states that this identifier is assigned by the system. Therefore, not attribute expect to populate when uploading a new document?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.10.1; Line 493	5	Added clarifying text (as assumed) A unique identifier will be assigned to a document when it is first uploaded to the UPD. The ID assigned to the document <del>once it is uploaded to the UPD system must be specified. This identifier</del> is specific to this specific version of the document. Any new versions will get a new ID. This unique ID...	Change applied.
Section 1.10.1; Line 493	5	Changed for more clarifying text (as assumed): The status of this document must be specified as a Term ID based on the following values: - "current": This is the current <del>reference for</del> version of this document. superseded": This version of has been superseded by another version. - "entered in error": This version was created in error. Add after the link: ;only the terms stated above to be used	Change applied.
Section 1.10.2; Line 494	3	We can see the need for the status "superseded" in the UPD, but would this status not naturally be the result of a submission of a new version of the "same" document (identical product/type/country/language)? It seems unnecessary to require both submission of the new version and submission of an additional "Attached document" data structure in order to mark the superseded document as superseded.	Change applied.
Section 1.10.2; Line 494	2	"Entered" is not necessarily an intuitive term for a reference created in error.	The value has been renamed to 'entered-in-error'.
Section 1.10.2; Line 494	6	"Entered" is misleading Does this mean that wrongly uploaded documents cannot be deleted? Proposed change: „entered" to be replaced by „entered-in-error"	The value has been renamed to 'entered-in-error'.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.10.2; Line 494	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.
Section 1.10.3; Line 495	6	RMS list to be updates, SPC identifier is for human use und should be replaced by Vet-ID	Resolved by RMS team.
Section 1.10.3; Line 495	7	The RMS list "Product information document type" has been updated so this should be reflected here. Examples could be provided: Examples: Summary of Product Characteristics (100000155532), Package Leaflet (100000155538), Combined File of all Documents (100000155539)	Change applied.
Section 1.10.3; Line 495	7	Public assessment report is a term belonging to the regulatory authority submission unit type (100000155552), the reference to this list shall be added in the table value- Listed in Product Information Document Type (RMS list ID 100000155531) and in Regulatory Authority Submission Unit Type (RMS list ID Listed in Product Information Document Type (RMS list ID 100000155552)	Change applied.
Section 1.10.3; Line 495	7	However, it should be noted that the PuAR will not be sent at the end of the procedure as it is a document that is prepared only once the procedure is closed.	The PuAR can be provided also after the procedure is closed.
Section 1.10.3; Line 495	8	As already commented at CMDv, there should also be a document type for the combined PL/LAB.	Resolved by RMS team.
Section 1.10.3; Line 495	9	Not all terms exist in the RMS List. Are you liaising with SPOR for these to be added in RMS - in all environments (Dev, SIT, UAT & PROD)?	Resolved by RMS team.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.10.3; Line 495	9	User guidance and the rules. Is the rule mentioned the only one? The rules related to the document types will be captured here, i.e., there must only be one document type per product/per language/per member state (e.g. there can't be 2 SPCs in French in Belgium)	Change applied.
Section 1.10.3; Line 495	5	Add the terms now available and additional terms that is allowed (e.g. SPC/PL)	Change applied.
Section 1.10.4; Line 496	5	Why is "application/pdf" stated as value? Should probably be something else.	We will only accept documents with media type of 'application/pdf' which is a recognised IANA type.
Section 1.10.5; Line 497	2	AnimalhealthEurope supports the upload into the UPD of documents in relation to language (vs. country/language combination) as this is expected to steer towards fully common SPCs for countries within an MRP/DCP/RUP that share common languages. In addition, it will align on current practice for CAPs, for which only one version in each language is required.	Change applied.
Section 1.10.5; Line 497	9	Value: it is not an RMS list as it is not allowed here by FHIR. Must be: One of the official languages in the EU in the list of languages BCP-47.	Change applied.
Section 1.10.6; Line 500	5	The ISO Element Name and Path should be Content/MedicinalProduct/AttachedDocument/Content	Change applied.
Section 1.10.7; Line 501	2	It is questioned whether a document title is needed since a document type is already available. If yes, the document title could be computed based on document type and product name in English. Please note that the abbreviation "SmPC" is more used in human pharma and for historical reasons. A decision on the use of "SPC" or "SmPC" should be made for clarity and coherence.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.10.7; Line 501	5	An introduction should be added. It is not clear what we expect, i.e. a specified name or the file name to appear (like the examples).	Change applied.
Section 1.10.8; Line 504	6	References to the Product ID or Permanent ID that the document covers should be specified, as applicable. Means "as applicable" that in case of documents related not only to VMP but to the MAH in general for example, these references do not apply? Otherwise it will be difficult to load up e.g. the QPPV statement, summaries of inspection reports as inspection outcomes when the inspection was not product related etc.	As applicable, means that the list of product permanent ID that the document covered needs to be referenced. All the cited documentation i.e. QPPV statement etc are out of scope of UPD submission.
Section 1.10.8; Line 504	9	User guidance - is it correct that document can have reference to Product ID? I thought DocumentReference will only linked to Permanent ID i.e. to MedicinalProductDefinition/id	Change applied.
Section 1.11; Line 507	2	The inclusion of parallel traded products is not clearly defined	Change applied.
Section 1.11; Line 508	9	Reword first sentence from "This class enables to cross-reference one or more veterinary medicinal products as available into the UPD."	Change applied.
Section 1.11; Line 515	9	The terms listed here don't exist in lower environments and are only in PROD. Plus please review term id in PROD 200000013183 as has description "Informed Consent (Article 21 of Regulation (EU) 2019/6)". Doesn't include the word "application" which is included in IG	List and term names aligned between SPOR and IG; all terms available in all environments.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.11; Line 518	7	Rules will have to be detailed for generic/hybrid products with a reference product withdrawn : how the MAH could request the creation of a withdrawn reference product, who will insert the VMP in the database, under which timelines... What about non-current terms ex: MAH (OMS data), other data needed which are in RMS/SMS lists.	The approach is now described in the section for the product cross-reference identifier.
Section 1.11; Line 519	7	Rules for generic or hybrid products with more than one reference product shall be described : "In case, the generic or hybrid products refers to more than one reference product, the class is repeatable and data fields "Product cross-reference type" and "reference product identifier" shall be provided for each reference product".	Change applied.
Section 1.11.1; Line 530	6	Table, user guidance: last bullet point: if the legal basis is...1.6.1 for Par Trade there is only regulatory entitlement, Change: reference to section 2.1 (see line 598)	Change applied.
Section 1.11.1; Line 530	9	Term 200000016179 "Parallel trade of" only exists in PROD and not the lower environments.	All terms available in all environments.
Section 1.11.1; Line 530	3	In the table, the start of the User Guidance is not quite correct – what needs to be specified is the type of the cross-reference (relation), not the type of the product that is referenced.	Change applied.
Section 1.11.1; Line 531	5	Add missing text: If the legal basis specified in the field 1.6.1. is "Parallel traded product as referred to in article 102 of Regulation 2019/6", then "parallel trade of" respectively "parallel trade in reference of"	Change applied.
Section 1.11.1; Lines 531-532	3	The examples given are misleading.	Change applied.
Section 1.11.1; Line 532	2	Examples are not fully aligned on the User Guidance for Product cross-reference type	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.11.2; Line 533	9	Value(s) remove the "s" from the end of IDs as only one ID is provided per crossReference class	Change applied.
Section 1.11.2; Lines 533-535	3	These elements must contain one single identifier.	Change applied.
Section 1.11.2; Lines 533-535	6	Please verify FHIR Element and Path and example	The FHIR Path for Reference product identifier of MedicinalProductDefinition.crossReference.product Reference is correct. FHIR Element Name corrected. The example correctly shows the value to be populated for this reference.
Section 1.11.3; Line 536	7	The source product identifier is only required for parallel trade products, the conformance shall be "Conditional" instead of "mandatory".	Change applied.
Section 1.11.3; Line 536	9	Value(s) remove the "s" from the end of IDs as only one ID is provided per crossReference class	Change applied.
Section 1.11.3; Line 536	3	The Conformance of this element must be Conditional, based on whether the submitted product is parallel traded or not.	Change applied.
Section 1.11.3; Lines 536-538	6	Please verify FHIR Element and Path and example	The FHIR Path for Reference product identifier of MedicinalProductDefinition.crossReference.product Reference is correct. FHIR Element Name corrected. The example correctly shows the value to be populated for this reference.
Section 1.11.3; Line 536	9	Is this information necessary? Isn't the current product the source product and we only need to specify the reference product and reference type?	Change applied.
Section 1.11.3; Line 536	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.12; Line 542	5	<p>"...manufacturing site that performs any operation with regards to the manufacturing of the finished product as reflected in the quality part of the dossier and the eAF.</p> <p>"This section describes the operation(s) being performed by the manufacturing site for a veterinary medicinal product (including activities related to the manufacture of the active substance as applicable). Operations to be selected should be in line with the information included in relevant parts of the dossier and the eAF"</p> <p>We need to agree on the level of information to be included in the UPD. Only batch release sites are required for legacy data. If we include other manufacturers we will have problems in data consistency and harmonisation when dealing with variations, i.e. if a new manufacturer of e.g. an intermediate product is introduced via a variation and is then published in the UPD, it would look like this is the only manufacturer. Or, should it be introduced for new authorisations only? However, this will also be difficult to handle e.g. when handling technical groupings in a consistent way where both old and new products are involved, since some would have the manufacturers and others not.</p>	As stated in Chapter 4, for legacy data only batch release manufacturer is required.
Section 1.12; Line 543	7	<p>We will need a new section "1.12.3 Note" with free text. Indeed, we will need to specify for instance which site is responsible for which packaging of the VMP. Ex : site A is responsible for packaging in bag, site B is responsible for blisters...</p> <p>This "note" should be optional and detailed the manufacturing activities as described in the eAF.</p>	This is not in scope for the minimum viable product to capture the manufacturers for packages. This could be in a future scope to be agreed and prioritised, if required.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.12.1; Line 548	9	FHIR allows multiple manufacturers, but this is not supported by PMS LDM/PDM. This is the comment from the LDM "Each Manufacturing Business Operation may be undertaken by at most one Manufacturer Establishment". Therefore, Repeatable should be no.	Change applied.
Section 1.12.1; Line 548	9	Repeatability is not supported by the PDM, so the whole class must be repeated and not the manufacturer.	Change applied.
Section 1.12.2; Line 549	9	There is confusion about which term ID should be used to indicate the Manufacturing activity for Batch release (minimum data requested for legacy data).	Change applied.
Section 1.12.2; Line 561	9	Repeatable is not correct. FHIR only supports one type.	Change applied.
Section 1.12.2; Line 564	7	In the section examples, the value "Manufacture of active substance" should be deleted as we will not store this information in the UPD currently and the example "Batch certification" could be added : "Example(s): Processing operations for the medicinal product (100000160413), Quality control testing of medicinal product (100000160408), <del>Manufacture of active substance (100000160467)</del> , Primary packaging (100000160463), Manufacturer responsible for batch certification (100000160407)"	Change applied.
Section 2; Line 566	9	Could we have a class for the entitlement in this section indicating that is mandatory and repeatable? Similar to other sections in the document.	Change applied.
Section 2; Line 584	4	"If a registration for a homeopathic veterinary medicinal product is granted, the organisation is referred to as a registration holder."	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2; Line 585	5	Added text for clarification [...] granted, the organisation is referred to as a registration holder, in this document included in the term marketing authorisation holder (MAH).	Change applied.
Section 2; Line 599	5	Added text for clarification [...] a wholesale distributor. (Please note, the MAH of the source product is still responsible for the product even if it is registered for parallel trade in another destination country.)	Change applied.
Section 2.1; Line 607	9	Do the 'veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6) of Regulation (EU) 2019/6 or exempted from the provisions in Articles 5 to 8 of Directive 2001/82/EC in accordance with Article 4(2) of the same Directive' have entitlement type value 'Marketing authorisation' always? - Are the examples the only values applicable to this field?	The requirements for Article 5(6) products will be discussed at a later stage, as including those in the UPD is only mandatory from 2024.
Section 2.1; Line 614	7	Examples shall be amended with the RMS ID of the terms provided: "Example(s): Marketing authorisation (220000000061), Homeopathic registration (200000015756), Parallel Trade Authorisation (220000000063), Veterinary medicinal products intended for animals exclusively kept as pets (200000016178)"	Change applied.
Section 2.1; Line 614	9	Can we add in the examples the following value: Veterinary medicinal products intended for animals exclusively kept as pets?	Change applied.
Section 2.2; Line 615	9	Only one MA number (the current one) can be referenced in this data element. Any change of an MA number triggered by, for instance, a transfer of MAH e.g. in Ireland should be recorded as a new version in this field.	Change applied.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.2; Line 615	9	The EU IG needs to be updated to reflect that the entitlement number will be provide or at package or at product level. No root number will be requested in the guide.	Change applied.
Section 2.2; Line 615	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.
Section 2.2; Line 618	4	This sentence seems to be incomplete: "If the MA number was assigned by the EU Commission, then the MA number as stated in SPC"	Change applied.
Section 2.2; Lines 621-622	4	To be noted: Not all NCA will fill the MA number in the SPC, but there is a certificate with the MA number.	Noted.
Section 2.2; Lines 621-628	5	To delete irrelevant wordings (probably copied from the human IG, related to art 57) and also minor changes.	Change applied.
Section 2.2; Line 624	8	A transfer of a MA to a new MA usually doesn't change the MA number. MA numbers don't have versions at all in AT.	Noted, you will always use the latest verison of the product ID.
Section 2.2; Line 635	5	Change the text a bit: <del>This section could also contain</del> For products that are not authorised medicinal products, this section should be used for:	Change applied.
Section 2.2; Line 640	5	It would be enough with just keeping the first sentence in the User guidance, since the three bullet points under are just a repetition of text given above.	Rejected.
Section 2.2; Line 641	8	See above. At least for MRP/DCP and NAPs the MA numbers are never amended.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.2; Line 641	9	FHIR Path: "RegulatedAuthorization.identifier.value with reference to the MedicinalProductDefinition resource ". Is this clear enough "with reference to the MedicinalProductDefinition resource". What we mean is that RegulatedAuthorization.subject is reference to MedicinalProductDefinition resource. But await recommendation of how RegulatedAuthorization should be populated.	Change applied.
Section 2.2; Line 641	4	Table "TAG – DESCRIPTION", section "VALUE" the hyperlink goes to a page that no longer exists	This URL is to be understood as a URI and is not navigable.
Section 2.2; Lines 643, 646, 650	5	Start the examples with some product level IDs Example of MA number on product level: 123456, 9743/2016, EU/2/13/016 Example 1 of MA number on package level: Example 2 of MA number on package level:	Change applied.
Section 2.3; Line 656	8	AT will create and updates products for LI based on a separate permanent identifier.	Confirmed.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.3; Line 656	9	<p>Is the country grouping expected for all values related to country or it doesn't need to be provided by the user (e.g. 2.3. was required in July and not anymore).</p> <p>Can the guide specify which values could be selected by the user in each one of the 'Country' fields (we need to filter by Country grouping for example)?</p> <p>The section 2.13.3 Procedure type - 'authorised' DCP MRP RUP and NAP products, states that 'The authorisation country must have been specified as one of the EEA countries in section 2.3 "Country".</p> <p>In RMS we have 3 different EEA country grouping: European Economic Area - EEA   EEA excluding UK(NI)  EEA and UK(GB) which one applies here? Can we specify that in the guide?</p> <p>For CAP products other rules apply with respect to country 'EU' or 'LI'/'NO'/'IS'</p> <p>Do we need to control the values that in country must be provided? (in all sections) So must be 'EU' the country for CAPs in 2.3? If that's the</p>	Change applied.
Section 2.4; Line 659	6	Shouldn't the data type be 'codeable concept'?	The data type is an identifier from OMS.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.4; Lines 659ff.	4	Some tables do not have examples. We wonder if this is intentional, as some other tables in this section provide examples. Tables with no examples: 2.4. Responsible authority (organisation) 2.6. Date of authorisation status change 2.7. Marketing authorisation date 2.8. Product owner (organisation) 2.9. Source wholesale distributor (organisation) 2.10. Destination wholesale distributor (organisation) 2.11. Reference member state 2.12. Concerned Member states	Noted.
Section 2.4; Line 659	5	Add ISO references ISO Element name: Identifier ISO Path: /MedicinalProduct/MarketingAuthorisation/Organisation(MedicinesRegulatoryAgency)/Identifier	Change applied.
Section 2.4; Line 659	9	Why is it a reference to an RMS list in which terms denote organisations without even a mapping to the corresponding organisation in OMS? Is that common with H domain?	Change applied.
Section 2.4; Line 659	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.5; Line 660	7	<p>The impact of the change of the authorisation status throughout the lifecycle of the product on the Product status 1.2 shall be described:</p> <p>"The authorisation status of a product could change throughout its lifecycle. A status "Valid" or "Suspended" leads to a product status "CURRENT", a "Pending" status leads to a product status "PROVISIONAL", a product with an authorisation "Revoked" or "Withdrawn" has a product status "NON-CURRENT"."</p>	<p>Information related to the statuses that a product can have throughout its lifecycle is described in the section 1.2 Product Record Status.</p> <p>A product in UPD can have the statuses current, provisional and nullified, therefore non-current has been removed from the IG.</p> <p>Although it is true that there may be a relationship between the MA status and the product status, the product status' transitions are not triggered by changes in MA status.</p>
Section 2.5; Line 660	5	Propose to set a term for the authorisation status during the period of End-of-procedure and Authorisation, if this can be done automatically when the RMS creates the products.	Change applied.
Section 2.5; Line 661	7	<p>Example(s):</p> <p>Valid (100000072099), <del>Expired (100000072100)</del>, Revoked (100000072121), Withdrawn (100000072113), Pending (220000000066), Suspended (100000072122)</p>	Change applied.
Section 2.8; Line 665	7	The excel file "change liaison" has an additional data "type of marketing authorisation date" that should be either added here or deleted in the excel file.	The document provided to vet change liaisons what a draft snapshot of the situation at the time, please refer only to the overview provided in Chapter 4 as published.
Section 2.8; Line 665	9	Has been added that "Not applicable for parallel traded veterinary medicinal product.". Conformance is still Mandatory. Lines 605-606 state ". (Please note, the MAH of the source product is still responsible for the product even if it is registered for parallel trade in another destination country.)". Should this be Conditional now?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.8; Line 665	5	Product owner cannot be mandatory for parallel traded products since the wholesale distributor is responsible for putting the product on the market.	Change applied.
Section 2.8; Line 665	3	Product owner is specified as Mandatory and Destination wholesale distributor as Conditional. For a parallel traded product, this would mean that the same organisation should be specified as both Product owner and Destination wholesale distributor. This seems unnecessary.	Rejected - the product owner remains the MAH whilst the company holding approval for parallel trade is the destination wholesale distributor. (See Commission Implementing Regulation (EU) 2021/16)
Section 2.9; Line 668	9	User guidance and Conformance have different criteria as to when this applies. One is based on legal basis and one on the authorisation/registration/entitlement type. Expected they would be referring to the same data element.	Change applied.
Section 2.9; Line 670	6	Please specify FHIR Element Name	We have removed the name as it is included in the fully qualified FHIR path.
Section 2.10; Line 672	4	This part of the sentence "Wholesale distributor who is providing the parallel traded veterinary medicinal product..." seems to refer to section 2.9 (instead of 2.10).	Change applied.
Section 2.10; Line 672	9	User guidance and Conformance have different criteria as to when this applies. One is based on legal basis and one on the authorisation/registration/entitlement type. Expected they would be referring to the same data element.	Change applied.
Section 2.10; Line 673	9	FHIR path is wrong - missing extension	Change applied.
Section 2.11; Line 674	6	Please verify FHIR Element and Path	We have removed the name as it is included in the fully qualified FHIR path.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.11; Line 675	5	Correction Name of the Reference Member State to be stated in the case of decentralised marketing authorisation procedure (DCP), mutual recognition procedure (MRP of national marketing authorisations or subsequent recognition procedures (SRP). <del>A reference member state is also assigned to veterinary medicinal products subject to</del> and an SPC harmonisation.	Change applied.
Section 2.11; Line 677	7	It is proposed to mention clearly that the VMPs subject to SPC harmonisation will be transferred to MRP. So we propose to reword as: "A reference member state is also assigned to veterinary medicinal products subject to mutual recognition following a SPC harmonization"	Change applied.
Section 2.12; Line 679	6	Please verify FHIR Element and Path	FHIR Path is correct. FHIR Element Name has been corrected.
Section 2.12; Line 680	7	Proposal for a rewording as the words "decentralised MA" is mentioned twice and clearly explained that products are transferred in a MRP after a SPC harmonisation. "Names of the Concerned Member States (CMS). Only in the case of decentralised marketing authorisation, mutual recognition of national marketing authorisations or subsequent recognition (RUP), and mutual recognition following SPC harmonisation."	Change applied.
Section 2.12; Line 680	5	Names of the Concerned Member States (CMS) should be specified. Only in the case of decentralised marketing authorisation procedure (DCP), mutual recognition of national marketing authorisations procedure (MRP) or subsequent recognition (RUP) (SRP), decentralised marketing authorisation procedures and an SPC harmonisation.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.12; Line 680	9	2.12 Concerned Member states to be 'Concerned member states' lowercase as used in 2.11	Change applied.
Section 2.13; Line 683	7	The class only refers to the initial marketing authorisation procedure and should be updated for National Procedures that become MRP following SPC harmonization or referral procedures : "Marketing Authorisation Procedure class is used for submitting information related to the initial Marketing authorisation approval routes (e.g. Centralised Procedure, Mutual recognition Procedure, Decentralised Procedure and National Procedure) and for the national procedures transfer in a MRP (following SPC harmonisation or referral) <del>and regulatory procedure applications (e.g. initial marketing authorisation application, variations, transfers, etc.)</del> , that impact the product information as included in this guidance. The class is mandatory for veterinary medicinal products authorised in the EU/EEA."	Change applied.
Section 2.13; Line 687	8	The term "product information" is used for the documents SPC/PL/LAB. But I think here it means all info about the product, so also the data. This is confusing.	RMS list has been reviewed.
Section 2.13; Line 688	4	Table "CLASS OF PROCEDURE – DESCRIPTION" seems incomplete (if compared to others)	No change. The class tables only show these two entries.
Section 2.13.1; Lines 701, 714, 717, 723 and 732	5	Specify that only the core procedure number should be stated as Procedure number (to be able to search for all concerned products within an MRP, regardless which initial procedure that led to the inclusion in the MRP "cluster").	Change applied.
Section 2.13.1; Line 710	4	Consider additional types of application, i.e. -Renewals (to be confirmed and as for Commission clarification on transition from Directive to Regulation) -Variations	No change. Can be added at later stage if required.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.13.1; Lines 724-725	4	Hyperlink directs to a search results page on the EMA website, not to a specific page or document.	Change applied.
Section 2.13.1; Line 730	4	Table "TAG – DESCRIPTION", section "Value" It should be noted that the format for Centralised Procedure is different	Change applied.
Section 2.13.2; Line 733	5	This is a PMS extension – the Cross-Reference attribute in IDMP is not suitable for this since the cross-reference must refer to another product. The FHIR path is not correct either since this is not related to the case. A new attribute at the MedicinalProduct level must be created for this. How can the Conformance be Conditional? All products must have this ID.	The conformance is mandatory as at the creation of the product it does not exist yet. Modified to correct the description and the mapping.
Section 2.13.2; Line 733	9	If the identifier is to be generated by UPD then it is not optional at product creation, it must not be provided at product creation; why 'Editable'?	Change applied.
Section 2.13.2; Line 733	9	ISO paths are related to cross references on Medicinal Product level, I understand the type of product identifier mentioned in this section is not a reference to another UPD Product. Therefore the ISO path is not applicable.	Change applied.
Section 2.13.2; Line 737	6	Please verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.
Section 2.13.2; Line 737	9	User Guidance - is this ID value generated by the system; or input by the user? First statement says the system will generate. In which case is conflicting to say that it's optional at time of creation. And is it correct that this is Editable?	Change applied.
Section 2.13.2; Line 737	9	Typo in section heading	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.13.3; Line 739	5	The type of procedure ( <del>EU medicinal marketing authorisation approval routes</del> ) through which the initial marketing authorisation in accordance with article 44, 47, 49, 52, 53 or 54 of the Regulation (EU) 2019/6 was granted <del>by the regulatory authority</del> must be specified.	Change applied.
Section 2.13.3; Line 764	7	Add to the examples provided: "Subsequent Recognition Procedure (200000016181)"	Change applied.
Section 3; Line 765	7	The title "pharmaceutical products is to be renamed into "administrable products"	Explanation in text applied.
Section 3; Line 765	8	Is the pharmaceutical form an attribute of the pharmaceutical product? We didn't find this attribute in this section.	Attribute has been removed.
Section 3; Lines 765-767	7	This section is not clear: we have issues to see how the routes of administration/target species/withdrawal period are organised and linked to the VMP. And this should also be reflected in the conceptual data model.	Change applied.
Section 3; Lines 765-768	6	When there are more than one route of administration, i.e. intramuscular + subcutaneous, at which level will the repetition take place (route of administration (768) or pharmaceutical product (765), Route of administration is NOT repeatable in the guidance.	Change applied.
Section 3; Line 765	9	Note that FHIR resource of AdministrableProductDefinition cannot be expressed without: * administrableDoseForm (hard constraint, it is required as per May2020 but not as per Sep2020); * ingredient (soft constraint, legacy from the previous IG, can be changed)	Change applied.
Section 3; Line 766	5	Add text to further clarify why the section Pharmaceutical product is included in the vet IG although not really used for the vet products.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3.1; Line 768	7	The words "of the pharmaceutical form" should be deleted as a route of administration is not specified to 1 pharmaceutical form. "User Guidance- The route of administration of the pharmaceutical form must be specified in accordance with the appropriate Section of the SPC as a Term ID."	Change applied.
Section 3.1; Line 768	8	One product can have more than one route of administration. Why is it not repeatable? Do we understand correctly that for multiple route of administrations multiple pharmaceutical products are necessary? This does not use useful.	Change applied.
Section 3.1; Line 768	9	The guide under consultation states that Route of administration is not repeatable but should be repeatable.	Change applied.
Section 3.2; Line 772	9	Conformance is Mandatory, however first sentence in User Guidance says "(if available)". The target species as indicated in the appropriate section of the corresponding SPC must be provided (if available) as a term ID. If multiple values apply to the same veterinary medicinal product then multiple values must be selected.	Change applied.
Section 3.2; Line 772	2	Will the target species as indicated in this field also translate to the OPAD species split, e.g., do we have to report on cats and kittens separately?	Granularity of target species does not necessarily relate 1:1 to the species used for the OPAD species split.
Section 3.2; Line 772	9	Deleted target species should not be removed from the database ('not physical delete'). MAHs will need the references to these target species in order to submit volume of sales.	The documented behaviour of deletions remains as agreed; this will have no impact on volume of sales reporting.
Section 3.3; Line 775	3	The data element Withdrawal period is presented as optional. Is that the intention?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3.3; Line 775	9	Withdrawal period class is optional and tissue, period and note fields as well. Can we have a withdrawal period with tissue and no period or vice versa? Also only note and not tissue or period?	Change applied: tissue and period are mandatory as per FHIR standard.
Section 3.3; Line 780	7	The withdrawal period should be linked to the "administrable product" and not to the "pharmaceutical product" cf comment 765 – 767. "Each withdrawal period will belong to a <del>pharmaceutical</del> an administrable product on which one route of administration and one or more species are described."	No change.
Section 3.3.1; Line 782	9	If a withdrawalPeriod class is included, tissue is mandatory in FHIR R5 Preview 2	Change applied.
Section 3.3.1; Line 782	5	Please add some clarifying text: As listed in Tissue (100000072054) Only values with extended attributes of "Tissue type" being "Edible and MRL Tissue", "MRL Tissue" or "Edible Tissue should be used".	Change applied.
Section 3.3.2; Line 785	9	If a withdrawalPeriod class is included, value is mandatory in FHIR R5 Preview 2	Change applied.
Section 3.3.3; Line 788	7	It is unclear in the proposed structure if the note should be linked to a specific tissue or directly to the animal species concerned. E.g. Should we select "milk" as a "Tissue" when the following note is mentioned in the SPC: "Not authorised for use in animals producing milk for human consumption." If yes, as there is no period of time for milk approved, the withdrawalperiod.value cannot be filled in. A description should be added to the point 3.3.3 or in the chapter 6 Examples : "When the following note is mentioned in the SPC: "Not authorised for use in animals producing milk for human consumption", there is no period of time for milk approved, the tissue and the period shall be left blank".	The figure on the model has been added, which clarifies the relation with target species.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3.3.3; Line 788	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.
Section 4; Line 793	9	To remove the part 'Also, the same ingredient can be referenced in both the manufactured item and pharmaceutical product, when needed' since ingredients are not going to be provided for pharmaceutical product section.	Change applied.
Section 4; Line 795	9	States "Note that when describing ingredients of manufactured items (section 6.6.4), only the active substance should be provided as mandatory." This suggests that optionally could also add Ingredient for non-active substances. Which contradicts 4.1 Ingredient role where only valid option is Active	Change applied.
Section 4; Line 796	5	We should be clear if other substances than the active substance are expected at all in the UPD. According to the text in the Description, ONLY the active substance should be given (only that term for the role should be used). It would be good to have this harmonised so that we just state the active substance until we agree to add more substances, harmonised. Since we don't use the Pharmaceutical product concept in the UPD, this below sentence should be deleted.	Change applied.
Section 4; Line 796	5	Correct the ISO Path.	Change applied.
Section 4; Line 796	9	States "Also, the same ingredient can be referenced in both the manufactured item and pharmaceutical product, when needed." But we no longer have ingredients references from pharmaceutical product.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.1; Line 801	7	Some manufactured items don't contain any active substance, in this case the ingredient role remains "Active", an explanation shall be provided in the point 4.1 or in the chapter 6 examples : "User Guidance- The role of the ingredient as part of the manufactured item must be specified as a term ID. In case the product doesn't contain any active substance, the excipient included in the product is fulfilled as an active ingredient (eg water for injection)".	Clarification provided.
Section 4.1; Line 801	9	The User guidance in the table indicates 'The role of the ingredient as part of the manufactured item must be specified as a term ID' Since the user can provide ingredients that are not active substance (in the context of the Manufactured item), would be possible to remove the restriction of providing always the term for 'Active'?	Change applied.
Section 4.2; Line 805	8	But it may be entered optionally. Optional population is possible?	Confirmed.
Section 4.3; Line 806	7	A table should be added to describe the Substance class: repeatable and mandatory.	The ingredient class is the substance class.
Section 4.3; Lines 806	3	It seems to us that the Substance class does not correspond to a natural grouping of data: The ingredient class has a role and a substance with manufacturer(s), strength and possibly reference strength, but only the ingredient class itself is a repeatable grouping.	Rejected.
Section 4.3.1; Line 806	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3; Line 807	7	<p>Why are the reference active substance and the reference strength not listed first as this information is common to all active substances whereas salts/hydrates/esters do not apply to all active substances (e.g. florfenicol, praziquantel, tulathromycine, pimobendan, etc.).</p> <p>This will be in accordance with QRD Template that states that the quantity in active moiety is always required.</p> <p>In this case, the quantity of salt/ester will be optional depending on the active substance present in the finished product. This will avoid the repetition of the information for the active substance not present as (salt/ester).</p>	Clarification provided.
Section 4.3; Line 807	5	We should not use Pharmaceutical product	Change applied.
Section 4.3; Lines 810-811	3	The substance class cannot be repeated. If multiple active ingredients are to be specified, the Ingredient class needs to be repeated.	The class is repeatable.
Section 4.3.1; Line 813	6	Please verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.
Section 4.3.1; Line 813	5	<p>Propose to clarify what should be given as "active" substance where not obvious.</p> <p>NOTE: Every medicinal product must have at least one active substance. For products that are not regarded as having a real active substance, the "main substance" of the product should be given (e.g. sterile water, sodium chloride). For homeopathic products, the final dilution/trituration(s) added to the product should be stated.</p> <p>Change ISO Path to: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance</p>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3.2; Line 814	9	FHIR data type for all strength and reference strength values is "decimal". This only accepts a full stop as the decimal place. The examples have a comma. <a href="http://hl7.org/fhir/2020May/datatypes.html#decimal">http://hl7.org/fhir/2020May/datatypes.html#decimal</a>	Change applied.
Section 4.3.2; Line 814	5	A clarifying section with example/s regarding active substances of homeopathic veterinary medicinal products is required, including acceptable usage of different expressions for degree of dilution.  It would be good to talk to the human EU IG where a decision tree is being added that illustrates the different cases. That tree should be included also here and the text altered to go with the tree.  A pattern table for different types of products has also been included in the human IG and should be considered here.	Please refer to Chapter 6 (Examples).
Section 4.3.2; Lines 820-825	3	On "The expression of strength": The first sentence claims that "The expression of strength for a product is expressed as in the SPC in active moiety." The following sentences describe the exceptions to this rule. The final sentence seems to require that the strength of the active moiety should always be expressed by means of the Reference strength class. However the Reference strength class is later (4.3.3) described as optional.	Clarified in the text: conformance cannot be changed, human judgement must be applied.
Section 4.3.2; Lines 822-824	3	The test states that "Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the active moiety (free base, acid or anhydrous material)."  However, in the examples given, the strength is expressed in terms of the hydrate or salt.	Change applied.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3.2; Line 838	7	Examples shall also be provided for immunological products.	Please refer to Chapter 6 (Examples).
Section 4.3.2; Line 849	7	It is not "and/or" it is "or" because strength is provided by presentation or by concentration, not both.	Change applied.
Section 4.3.2; Line 849	5	And/OR: Please describe when presentation strength and/or concentration strength should be used. When are both strengths required?	Change applied.
Section 4.3.2; Line 853	5	The text is incorrect. The concentration strength is always per 1 unit of the denominator. If it is expressed as per 0.8 ml, then this is actually a presentation strength since the 0.8 ml would be the volume of the presentation. See suggestion for a new text.	Rejected - the denominator is the concentration of the substance, which might be different from the unit of presentation.
Section 4.3.2; Line 860	5	Concerning the sentence: "The provision of the strength(s) of the active ingredient(s) is mandatory. The strength of the active substance as listed in SPC and Part 2A must be specified." Check with the human EU IG about this. There we have adjusted what is mandatory based on how the product is described and how it is used (patterns and the decision tree mentioned above). we should not refer to the Pharmaceutical product in the vet IG in which a <del>Pharmaceutical Product</del> Manufacturing item is presented	Change applied.
Section 4.3.2; Line 862	5	How are you going to express ranges of strengths that occur, e.g. low limit and upper limit?	Change applied.
Section 4.3.2; Line 866	7	"Dose" should be added in the list "unit of presentation" and "unit of measure" for immunological VMPS.	Under review by SPOR team.
Section 4.3.3; Line 874	9	FHIR Element Name - should corrected to last element in FHIR Path.	Change applied.
Section 4.3.3; Line 876	5	It would be beneficial to reference the patterns and decision tree mentioned earlier, what strength expression to be used.	Rejected.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3.3; Line 879	9	Remove reference to pharmaceutical product	Change applied.
Section 4.3.3; Line 881	9	Since only active substances can be added, is this sentence now required? Potentially makes reader think they can add any ingredient with any role.	Change applied.
Section 4.3.3; Line 882	3	Please leave out the editorial comment in italics.	Change applied.
Section 4.3.3; Line 882	5	We do not understand the EXAMPLE: If maintained, use oxytet HCl / oxytet example above Oxytetracycline HCl / oxytetracycline (concentration strength). Also, could the value "1g" as Active and Reference the table be explained, i.e. where it would come from for this product.	Change applied.
Section 4.3.3; Line 887	6	Please verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.
Section 4.3.3; Line 887	7	Add "Reference active substance " as a title like Substance in point 4.3.1 before the reference strength in point 4.3.3 (line 874)	Change applied.
Section 4.3.3; Line 887	5	Change in ISO Path /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength/ReferenceSubstance	Change applied.
Section 4.3.3; Lines 889-891	3	Please reuse the wording of the lines 863-866, suitably adjusted.	Change applied.
Section 4.3.3; Line 891	6	Please verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.
Section 4.3.3; Line 891	9	FHIR path contains a comma and not a fullstop	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3.3; Line 891	5	<p>Correction proposed</p> <p>The denominator shall be expressed with a unit of numeric value and a unit of presentation (e.g. tablet) or a unit of measurement.</p> <p>The units for the denominator must be specified as a value and a Term ID as listed in Units of Presentation (200000000014) or Units of Measurement.</p> <p>/MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength/Strength</p>	Change applied.
Section 4.3.3; Lines 895-897	3	Please reuse the wording of the lines 868-870, suitably adjusted.	Change applied.
Section 4.3.3; Line 897	6	Please verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.
Section 4.3.3; Line 897	5	/MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength/Strength	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 5; Line 898	5	<p>1) Propose to move this whole section to section 2, right after section 2.13.2, the product identifier, level 1. Should not be a major section but at the same level as the product Identifier level 1.</p> <p>2) Heading: Please, Add (ID Level 2)</p> <p>3) Clarify text in user guidance: As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier <del>ensures that</del> differentiates between the veterinary medicinal products authorised in several Member States from the same MRP/DCP or RUP SPR. <del>are identified based on a set of</del> It is generated based on the Product ID (Level 1) with the addition of the national information as authorised in the country by the relevant competent authority and representing the so-called 'national entitlement'. Note: The Permanent Identifier data element will be given by the time of initial creation for products within CP, NP and Registration procedures but is <del>optional</del> left blank at the initial creation of the veterinary medicinal product within MRP/DCP into UPD.</p>	Change applied.
Section 5; Line 898	9	FHIR path is to the technical ID of the FHIR resource. Should this be a business identifier? FHIR path would then be .identifier with a system value of "updId" or similar.	Change applied.
Section 5; Line 902	3	The distinction between the Product identifier and the Permanent identifier is not easy to remember.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 5; Line 904	9	I thought this is a value generated by the system on a Create? Therefore not correct to include this sentence "The Permanent Identifier data element is optional at the initial creation of the veterinary medicinal product into UPD."	Change applied.
Section 5; Line 905	5	The attribute Package.quantity needs to be added in order for it to be possible to properly describe the medicine in its package. Also, it is important that it is a stable ID.	Change applied.
Section 6; Line 905	9	Deleted packages should not be removed from the database ('not physical delete'). MAHs will need the references to these packages in order to submit volume of sales.	Change applied.
Section 6; Line 905	9	Is it possible to have Packaged medicinal product information at 'class' level. It would help to understand if information on packages is mandatory and repeatable.	Change applied.
Section 6; Line 905	9	"The package description is to be provided by the RMS as part of the European/common data set for all the packages authorised under the regulatory procedures in in English, or in both." I don't understand what ", or in both." means. If package description is non repeatable, how to deal in DC MR procedures with the EN description provided by the RMS and the national ones provided by CMS?	Change applied.
Section 6; Line 905	9	It has been raised by the Product owner group that ingredient for manufactured item cannot be mandatory since it is not always possible to provide the active ingredient. (e.g. solvent for solution for injection)	Change applied.
Section 6; Line 913	8	A stable package id during the lifecycle is essential to enable data exchange. Please consider this aspect. Otherwise it will break data synchronisation.	This is supported by either the FHIR id for package product or by the package identifier.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6; Line 913	2	<p>To be able to report on sales volume, the IG notes that it is still under discussion whether a package identifier would be the PCID or just a system identifier. However, the current PCID concept is a "European" one. E.g., for MRP the CMS must specify by selecting, as part of the national data set, the applicable PCIDs as authorised in the relevant national territory among the available PCIDs as provided by the RMS. This is meaning that there will be no unique ID for a pack sold in a specific MS.</p> <p>In addition it is noted that the PCID data element is optional at the initial creation of the veterinary medicinal product into UPD. As sales quantity reporting will need to be broken down to the country and is dependent on a mandatory unique ID, it is unclear how mapping can be done based on the described concept of an optional European PCID. Instead, a unique system ID in the national data set appears to be better suited, as it allows direct mapping of pack sizes marketed in a specific country to sales quantities.</p>	<p>According to the Vet EU IG, in order to submit the volume of sales per package for an specific country, a MAH will need to provide the package identifier that is 'European' together with the country where the package has been sold. The Conditional conformance of the Package identifier is based on the operation type to be performed, i.e. for create it is not required since it will be generated by the system, and for updates will be mandatory. A specific chapter on volume of sales will be drafted.</p>
Section 6; Line 913	3	<p>Given that "PCID" is a well-defined term from IDMP and given that the UPD does not contain the MPID that constitutes a part of the PCID, please avoid referring to any human-readable UPD package ID as "PCID".</p>	Reference to PCID removed.
Section 6; Line 916	5	<p>Proposed clarification</p> <p>The English language package description as written in the approved SPC and in the End-of-procedure document is to be provided by the RMS as part of the European/common data set for all the packages authorised under the regulatory procedures.</p>	Change applied.
Section 6; Line 919	6	Proposed (editorial) change: PCIDs	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.1; Line 929	6	User guidance box of 6.1 is hard to understand. Can you please specify on which level the repetition shall occur (6, or 6.1).	A 'class' for package medicinal product has been added to provide more clarity.
Section 6.1; Line 929	7	A Packaged product class shall be added before 6.1 with "yes" at repeatable in order to have several package description/pack sizes for a veterinary medicinal product. The packaged product class shall include : - 6.1 package description, 6.1.1 Language, 6.1.2 Country - 6.2 Pack size - 6.3 Package identifier - 6.4 Legal status of supply - 6.5 Marketing authorisation (package level), 6.5.1 Marketing authorisation number (package level), 6.5.2 Country	A 'class' for package medicinal product has been added to provide more clarity.
Section 6.1; Line 929	2	6.1 Table: products authorised via CP: package description 'added by whom?' is missing - only mentioned for MRP/DCP/NP.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.1; Line 929	5	<p>Proposed change (if any): Proposed clarification</p> <p>The free text description shall contain information regarding only of one individual pack sizes. For multiple pack sizes the elements should be repeated to collect 1 pack size per free text description with the text descriptions making clear the differences between the packs.</p> <p>For MRP/DCP, the English version from the eAF can be used by the RMS to populate by the end of procedure. In many cases it will need to be edited (separated) so that each package description only describes one package.</p> <p>Products authorised through NP</p> <p>The package description is to be provided by the NCA in the local language(s) of authorisation in line with the national SPC.</p> <p>Products authorised through the centralised procedure</p> <p>The package description is to be provided in English and local language optional in line with the national translations of the SPC.</p>	Change applied.
Section 6.1; Line 929	3	<p>The first bullet of the User Guidance concerning MRP/DCP/RUP products seems to be incomplete or to contain text that should have been deleted.</p> <p>We suppose that package description in English is required and that the RMS may add package description in the official language(s) of their country.</p> <p>The description concerning CAPs does not state, who is to provide the description – please specify.</p>	Noted.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.1; Line 929	9	The user guidance allows to provide the description of a package in more than one language but this element is NO repeatable, how is that possible?	Although the FHIR standard only allows one description field to be associated with a package, the fact that this element is a free text field will allow the user to introduce more than one translation when applicable (e.g. Belgium could provide the description of the package in its three official languages in the same field).
Section 6.1; Line 931	5	<p>On all examples, add text in red as proposed below.</p> <p>1) If text is in the SPC Section 6.5 Nature and composition of immediate packaging is: Xxx The Information to be entered in UPD Package description of first package should be: Xxx Information about how to handle the blisters in the UPD are missing in the first example. Delete from SPC text or add description for the UPD. The examples in Spanish and French should be changed into English and information for UPD should be added or the example be deleted. Or, it should be clear that we have examples in the native languages (which is probably not very valuable in this IG). Add an example on combination packs, e.g.</p> <p>4) If text is in the SPC Section 6.5 Nature and composition of immediate packaging is: Boxes of 1 &amp; 10 vials of lyophilisate and 1 &amp; 10 vials of suspension The Information to be entered in UPD Package description of first package is: Plastic box of 1 dose + 1 ml vial Plastic box of 10 x 1 dose + 10 x 1 ml vial</p>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.1; Line 932	9	6.1 Package Description, please may the attributes be numbered all at the same 'level', e.g.: 6.1.1 Package Description 6.1.2 Language 6.1.3 Country	Change applied.
Section 6.1.1; Line 943	5	The given ISO Path will not work since this attribute in the ISO path is not coupled to the package. You need an extension just as you do for the language.	N/A in this section
Section 6.1.2; Line 946	6	In the user guidance box the word 'name' seems to be wrong here.	Change applied.
Section 6.1.2; Line 946	9	I don't understand this. Why is country included here as this is specified in section 1.7.3.1. There is no ability to link a PackagedProductDefinition resource to one particular MedicinalProductDefinition.name	Change applied.
Section 6.2; Line 949	3	The description only speaks of units of presentation but the example with one bottle of 250 ml naturally uses ml (unit of measurement) as the basis for the pack size.	Change applied.
Section 6.2; Line 949	9	Marketing authorisation status should be provided at package level when the authorisation is granted at this level, otherwise the value introduced at product level will apply to all packages (e.g. suspended). Also, we could align with the human domain in this point.	Change applied.
Section 6.2; Line 950	5	Add text for clarification: The pack size describes the number of units of presentation of a manufactured item in a packaged medicinal product, i.e. the numeric value and the unit of presentation.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.2; Line 958	7	"The pack size of a box of 1 bottle of 250 ml is 1 <del>250</del> (numeric value) bottle (unit of presentation), the quantity 250 ml is described in the (Manufactured idem quantity described in the manufactured item section)."	Change applied.
Section 6.2; Line 959	7	A packaged medicinal product has only one pack sizes. The "Packaged medicinal product class" is repeatable but the pack sizes field not. "Repeatable- No Yes"	Change applied.
Section 6.2; Line 959	7	Add an example of a pack size of a product with a vial of powder and a vial of solvent: "The pack size of a product with 1 vial of powder and 1 vial of solvent is 1 + 1."	Rejected - it is either 1 or 2 but not 1 + 1
Section 6.2; Line 959	9	There is no FHIR path. And how is this related to section 6.6.1?	Change applied.
Section 6.2; Line 961	7	Example(s): 10 (tablets), 20 (tablets), 2 (vials), 1 (vial of solvent) + 1 (vial of powder)	Change applied.
Section 6.2; Line 961	5	What if there are several manufactured items in one package? Please add examples for a package containing e.g. two vials, one with a powder and one with a solution.	Change applied.
Section 6.3; Line 962	9	First sentence states that this is assigned by UPD. i.e. the system generates this value. Therefore, not correct to also say is optional on create?	Clarification provided.
Section 6.3; Line 962	8	We assume that package identifiers are stable during the lifecycle of the package. Are there any rules for package identifiers in the context of data format? How is this identifier related with the IDMP PCID?	Yes the package ID is stable. As per the use of the package identifier, make sure that the value must not be supplied for CREATE but must be supplied for UPDATE. The package identifier will be generated by the system and must be seen as an opaque structure.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.3; Line 962	5	<p>“The PCID data element is optional at the initial creation of the veterinary medicinal product into UPD.”</p> <p>Is should be further described what “optional” mean here. Is it different for MRP/DCP (blank?) and CP, NP. And/or other reasons.</p> <p>Also, PCID or other ID to be defined (as discussed earlier in the document).</p>	Change applied.
Section 6.4; Line 963	7	Add package level to the heading 6.4 Legal status of the supply (package level)	Change applied.
Section 6.4; Line 963	5	Add text in heading for clarification Legal status of supply (package level)	Change applied.
Section 6.4; Line 963	3	<p>There is ongoing discussion in the SPOR Vet expert group about how to handle the cases where different pack sizes have different legal status of supply.</p> <p>Please revise the text to reflect the outcome of this discussion, if relevant.</p>	Noted.
Section 6.4; Line 972	3	The ISO Path given for Legal status of supply at package level seems to be incorrect (would seem to apply to the product level).	Since we have no requirement to align with ISO we have just retained in the documentation the mapping to the FHIR path which is now in line with the IG for human use.
Section 6.5.1; Line 993	7	The marketing authorisation number is not repeatable, only one number per packaged product. The “Packaged medicinal product class” is repeatable. “Repeatable- No Yes”	Change applied.
Section 6.5.1; Line 993	3	The conformance is specified as “Mandatory”. This is correct – but it presupposes that the 6.5 Marketing authorisation (package level) is relevant, which it is not always.	Change applied.
Section 6.5.2; Line 994	7	The country is not repeatable, only one country per packaged product. The “Packaged medicinal product class” is repeatable. “Repeatable- No Yes”	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.5.2; Line 994	5	Add text in heading for clarification Country (package level authorisation)	Change applied.
Section 6.6; Line 997	2	The section on "Annual volume of sales" which was present in previous drafts has been removed. Even if sales data input is handled by different tools (which is expected to be the IRIS platform) the sales data is remaining in scope of the UPD and a document is required that provides transparency on data field requirements. Proposed change: Reintroduce section on volume of sales.	Details on the formats for the submission of certain data by MAHs are still under discussion and will be included in a separate chapter on volume of sales.
Section 6.6; Line 997	3	Annual volume of sales is missing	Details on the formats for the submission of certain data by MAHs are still under discussion and will be included in a separate chapter on volume of sales.
Section 6.6.1; Line 1015	7	The "Manufactured item class" is mandatory, why the "unit of presentation" is Conditional? The condition shall be detailed if applicable. Proposal to have a conformance "Mandatory"	Change applied.
Section 6.6.1; Line 1015	9	What makes this conditional?	Change applied.
Section 6.6.2; Line 1018	5	Please, add an example describing how manufactured item quantity should be expressed for a package containing a powder and a solution Changed text proposed in bullet point two, for clarification	Change applied.
Section 6.6.2; Line 1018	9	Possibility to include the term 'dose' in Unity of measurement (EMA list) to allow the provision of information of Manufactured items like 'lyophilise for emulsion for injection'. If it is not possible then could be cases where several Manufactured Items could be exactly the same.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.6.3; Line 1024	5	Medicinal Product ABC 20mg/ml powder and solvent for solution for injection (combined pharmaceutical form) provided in two separate vials will contain two types of manufactured items with the following dose forms:	Change applied.
Section 6.6.3; Line 1032	9	This is mandatory in FHIR R5 Preview 2	Change applied.
Section 6.6.3; Line 1032	3	The Manufactured dose form seems to us to be Mandatory rather than Conditional.	Change applied.
Section 6.6.4; Line 1038	6	The implementation information is missing, seems to be incomplete	Please refer to section 4.
Section 6.6.4; Line 1038	7	According to 6.6.3 "solvent for solution for injection" is considered as a manufactured dose form. The quantity of ingredients in the case of solvent is not always clearly defined. E.g. citric acid qs pH 4.8; water for injections ad 1 ml. It should be also noted that the quantitative composition in excipients is not part of the Product information of the veterinary medicinal products (including solvents). We thus suggest to not require information on the quantity of ingredients except when the ingredient is the active substance.	Change applied.
Section 6.6.4; Line 1038	5	Remove the full section since it is not needed here in the context of Pharmaceutical product (concept not really used in vet products UPD). It is already described in the context of the manufactured item above.	The manufactured item ingredient describes the ingredient in the individual pack, which might differ from what is administered and described in the pharmaceutical product section, hence this section must be maintained.
Section 6.6.4; Line 1041	9	Table is missing showing user guidance, repeatable, FHIR path etc	Change applied (refer to section 4).
Annex I; Line 1042	6	The numbering in the last three lines of the table is wrong	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Annex; Line 1042	5	I think there is an Annex missing (Annex 2) where it is clarified what data elements that should be included for different product types.	Please refer to Chapter 6 (Examples).
Annex 1; Line 1042	3	Type for marketing authorisation date is not present in main text, only in Annex. What is meant by "type for...?"	Line removed from Annex.
Annex; Line 1042	9	We need a section or annex in the guide that specifies the fields that are applicable to registered homeopathics, parallel trade products.	Fields will apply to all products unless specified otherwise in the condition.
Annex 1; Line 1042	9	If any change made to Conformance, the corresponding entry in this Annex should be updated	Change applied.
Annex 1; Line 1042	9	Ref. 1.3 is mandatory	Change applied.
Annex 1; Line 1042	9	Ref. 1.6.2 Comment in brackets about MP or pack level is not applicable	Change applied.
Annex 1; Line 1042	9	Ref. 2.8 not listed in main document. The section numbers of the next two items in the table are not correct	Change applied.
Annex 1; Line 1042	9	Ref. 2.13.1 is conditional.	Change applied.
Annex 1; Line 1042	9	Ref. 4.2 In main document not required for UPD. Doesn't contain table of how might be populated if optionally want to include.	Change applied.
Annex 1; Line 1042	9	Ref. 4.3.3 the attribute and not the class is mandatory	Change applied.
Annex 1; Line 1042	9	Ref. 6.6 review section references - some are not correct and 5.6.2 (wrong number) is duplicate to line above	Change applied.
Annex 1; Line 1042	9	UPD IA Annex, i.e. IA Ref, 3.1 should be 3.10 for Withdrawal period tissue, period and note	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Annex 1; Line 1042	3	<p>It is not clear to us how much data needs to be submitted by the RMS for products approved according to MRP/DCP/RUP – for the individual “national” products in the different CMSs. We think that it is important to agree as soon as possible on the processes surrounding the UPD.</p> <p>The current description is to a large extent based on the data that needs to be found in the UPD after successful submission and important details on the processes seem to be still missing. The process for submission of “attached documents” is one additional example: should the document be submitted in advance in order to get the UPD identifier? – if so, why does the FHIR structure have the document content as mandatory?</p>	The RMS submits the common data and their own national dataset. The RMS only has to identify the CMSs, and subsequently the CMSs will submit their own national datasets. In this context, RMS would be expected to submit the english documents in the first instance, and then only their own language documentation with their national dataset after the product has been authorised in their Member State.
<b>Chapter 3</b>			
	2	The chapter does not provide any clarity or guidance on how MAH must process VNRA e.g. submit, upload.	Details on the formats for the submission of certain data by MAHs are still under discussion and will be included in the next version of the Veterinary EU IG as necessary (e.g. volume of sales or VNRA).
Section 2; Line 25-27	3	Please replace the comma between the two types of submission by “and” (for ease of understanding), resulting in the following text: “NCAs should electronically submit into the UPD information on newly authorised veterinary medicinal products and information on changes to existing veterinary medicinal products following completion of a variation procedure or another regulatory procedure, as applicable.”	Change applied.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2; Line 27	7	The upload of legacy data is not covered in this chapter, proposal to add upload of legacy data : "NCAs should electronically submit into the UPD information on existing veterinary medicinal products at the date of application of the VMP-Reg, newly authorised veterinary medicinal products, information on changes to existing veterinary medicinal products following completion of a variation procedure or another regulatory procedure, as applicable"	Rejected - specific legacy data provisions are addressed in chapter 4 - this chapter only relates to overall process.
Section 2; Line 37-40	3	According to this text, it is only foreseen that marketing authorisation holders may submit information to the UPD through the user interface. Marketing authorisation holders with many approved products will presumably want to use an automated process, using the API.	The exact scope of the API is under discussion by the product owners.
Section 2.1; Line 46	7	Are there specific endpoints for each type of product or type of procedure? If yes, please detail.	No there are not. Different profiles / business rules apply to each type of product/procedure as described in Chapter 2.
Section 2.1; Lines 55-57	3	The solutions mentioned are not described in Chapter 1.	Chapter 1 is an introduction, detailed description given in Chapter 3.
Section 2.1; Line 59	3	The wording "notify changes" sounds slightly inappropriate if the effect is an amendment of the existing information – just as in the previous bullet. Who submits and who is notified?	Change applied.
Section 2.1; Lines 66-67	4	This endpoint (data management operations) does not contain a number as others do (EP309 Create Product, EP311 Update Product). Is nullification not considered an operation?	The nullification of a medicinal product is done by submitting an update request with the product status NULLIFIED in its corresponding RMS term form.
Lines 77, 97, 116	3	The term "PCID" is used about the package identifier assigned by the UPD. This will be understood as "IDMP PCID".	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Lines 81-171	1	Regarding variations, it is unclear in which cases the NCA should submit the changed data to UPD and in which cases the MAH should submit the changed data to UPD. I suppose it should not be submitted from both.	This is specified in the implementing act and in the first 2 paragraphs of section 4 of Chapter 3; clarifying what the MAHs are expected to do. Anything else is the responsibility of the NCA.
Section 3.1; Line 117	7	Please define the timeline for CMS to update the product created by RMS.	For legacy timeline has been provided, for new ones, it's "after authorisation in the MS" so hard to define as they all have different timelines. Further clarification under way.
Section 3.2; Line 118	7	Is this chapter also applicable for legacy products once they have been uploaded in the UPD ?	Yes, also applicable to legacy data; details on which fields apply for submission of legacy data are provided in Chapter 4.
Section 3.2; Line 123	2	“(as well as renewal for products authorised before 28 January 2022)” Comment: This assumes that products authorised before 28/01/22 which have not yet been renewed must go through a renewal process. This is still under discussion and a Commission response is urgently needed.	Change applied.
Section 3.2; Line 130-132	2	The examples in parentheses (e.g., following variation...) refer to the ‘30 calendar days’, rather than ‘implementation’, so the sentence is confusing. What is the consequence if after 30 days the data isn't uploaded?	Change applied.
Section 3.2; Line 130-132	2	The IG states the requirement for NCAs to make the changes within 30 days but does not mention what happens if the deadline is not met. What is the consequence if after 30 days the data isn't uploaded?	This should be considered best practice, there are no legal deadlines at this point in time.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3.2; Line 130-144	1	Does this imply a requirement that the NCA is capable to deliver the information in FHIR format for all variations? From which date?	In legacy data, only submission of the latest version of product as authorised. Any subsequent changes need to be submitted to the UPD in line with these provisions.
Section 3.2.1; Lines 149-150	4	This sentence may be confusing since it seems that it is the MAH who can nullify the product in the UPD.	Change applied.
Section 4; Line 161-162	2	By the phrase 'once the regulatory procedure is completed', the 'Process' appears to be written only for dates of placing on market, availability status & suspension / revocation. However, it does not correctly describe the process for VNRA. As written, it implies that for VNRA 1) MAH submits a package, 2) CA approves 3) MAH updates UPD. This is not what is proposed and imposes an extra burden.	Details on the formats for the submission of certain data by MAHs are still under discussion and will be included in the next version of the Veterinary EU IG as necessary (e.g. volume of sales or VNRA).
Section 4; Line 171	9	Missing closing bracket after "EP311 Update Product"	Change applied.
Section 4; Line 172-173	2	MAH urgently need clarity on how and when details on the format for submission will be available.	Noted.
<b>Chapter 4</b>			
Scope; Line 26	11	Additional information on Page 3 regarding the status of products may be needed – exact date on which legacy MAs/registrations should be valid. Proposed text: "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 before 28 January 2022."	Change applied.
Scope; Line 26	2	From the MAH perspective, the IG does not provide any details on the legacy data upload timeline or organisation. More information and clarity on these aspects is desirable to reassure MAH that the upload will be completed in time for a meaningful period of MAH access, mapping and testing before going live.	Comment noted.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Scope; Line 38	5	authorised or registered in a Member State before 28 January 2022	Change applied.
Scope; Lines 43-44	8	What is the UPD product id? The permanent identifier should be sufficient to identify a medicinal product.	Correction applied.
Scope; Line 44	5	of a product record by assigning the UPD product ID (level 1), UPD permanent ID (level 2) and package ID	Change applied.
Section 1; Line 58	5	ad-hoc <del>temporary</del> file upload (single or batch).	Change applied.
Section 1; Line 59	5	<del>As a temporary</del> The ad-hoc file upload is a specific supporting measure to the initial upload of legacy data, where the Agency will accept XML.....	Change applied.
Section 1; Line 61	9	Clarification needed whether XML file will be sent by NCAs to the EMA Service Desk to upload it in UPD	Change applied.
Section 1; Line 63	5	NOTE 1: Should the XML file or any part of it (i.e.e.g. terminologies used) be recognised as not being compatible with the requirements when uploaded into the UPD system, the Agency will notify the NCAs and reject such submission with information on what failed. If the incorrect dataset is submitted as part of a batch upload, any correct datasets of that same bulk would be accepted as uploaded to the UPD.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1; Line 66	2	<p>NOTE 2: The Agency has the capacity to upload XML File(s) only once for each NCA. Therefore, this service shall be considered a temporary supporting measure and will be available only once and at the time of the legacy data provision by the NCAs before January 2022.'</p> <p>Comment: The submission planning roadmap in the Introduction chapter line 127-128 shows that the RMS uploads the common dataset and the CMS provide their national datasets subsequently. As each MS is an RMS for some product and CMS for others, it follows that there must be a least 2 submissions from each as the CMS data can only be added to a product after the RMS MS has made the 1st upload, as the UPD IDs of products created by the RMS are not known to CMS prior to creation of the records. The Agency must support at least 2 XML uploads.</p>	Change applied.
Section 1; Line 66	5	<p>NOTE 2: <del>The Agency has the capacity to upload XML File(s) only once for each NCA. Therefore, this</del> The ad-hoc file upload service shall be considered a temporary supporting measure and will be available only once and at the time of the legacy data provision by the NCAs before January 2022. The NCAs therefore need to prepare for the long-term submission strategy and adapt in-house systems accordingly for submissions after 22 January 2022, when only the API and the UPD user interface will be available for upload of data to the UPD.</p>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 2.6; Line 147	9	Some RMS List used by UPD are missing: EU Territorial Authority 2.4 Ingredient role 4.1 (always the same term) Marketing Status 1.5.2 Master File Type 1.8.1 (always the same term) Record Status 1.2 Tissue 3.3.1	Change applied.
Section 2.6; Lines 156-157	3	Ingredient role is missing in the RMS lists to be mapped	Change applied.
Section 2.8; Line 195-197	3	The update in question does not affect the substance ID but other attributes of the substance in the EUTCT list.	Change applied.
Section 2.8; Line 199	2	NOTE: At present, veterinary substances are undergoing cleansing in SMS. This is expected to be completed by end January 2021 at the latest.' Comment: Vet Substance Cleansing is still not completed (VMP-Reg Stakeholder meeting 25 Feb).	Change applied. The Vet Substance cleansing has been completed.
Section 2.8; Line 202	5	Concerning this text: "For Veterinary vaccines and proteins substances, the EUTCT lists do not currently include translations: if the substance name in English is provided for the relevant substance, the EUTCT ID shall be used to provide the veterinary product information in UPD. Meanwhile, a change request to update the existing substance ID shall be provided via the EMA Service Desk portal to submit the missing translation(s)." It is not clear from the text what is expected by NCAs concerning translations of these substances.	Those substances need to be provided.
Section 3; Line 226	6	Numbering of fields from IG chapter 2 is wrong (2.7 to 2.12)	Change applied.
Section 3; Line 226	6	'Manufacturing activity' should be 1.12.2	Change applied.
Section 3; Line 226	6	Table ends with 6.5.1, is this intentional?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	Specifically regarding point "1.10.6 Attached document content", it is according to us not realistic to provide this information within less than a year. The overall 1.10 section is technically very challenging. Even more for Belgium given the fact we also need to upload all documents in three languages. Moreover, from a technical point of view, uploading all the requested documents in the proposed format will make the upload too heavy.	Comment noted.
Section 3; Line 226	10	FAMHP is unable to deliver the data in code 64. The information regarding the upload of documentation has significantly increased. It is technically very difficult to upload the information and it is uncertain whether this information can be made available within the very strict timeframe. Specifically regarding point "1.10.6 Attached document content", it is according to us not realistic to provide this information within less than a year.	The use of base 64 encoding is only required for the manipulation of documents through the API as it is part of FHIR standard.
Section 3; Line 226	10	In 1.11.2 NCA's need to provide the permanent ID of the reference veterinary medicinal product. In practice this confronts us with the following issue: We need to link a generic VMP in our legacy data list to the ID of the reference VMP. However, if the NCA that has granted the marketing authorisation for the reference VMP, has not yet uploaded this reference VMP in the UPD, there is no possibility that we can link our generic product to the reference product identifier - since it doesn't exist yet. The same goes for 1.11.1 Product cross-reference type and 1.11.3. source product identifier.	Comment noted.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	We hold information on the QPPVs, however under another format as is requested. Moreover, we are unable to match the different QPPVs within one Belgian firm to the different products. We are thus very concerned on the quality of the data that we can deliver.	Comment noted.
Section 3; Line 226	10	2.12. Concerned Member States. This information is not available in our national databases. It is impossible for Belgium to upload these data.	Comment noted.
Section 3; Line 226	10	2.13.2. Product Identifier: It is indicated in the implementation guide that these data have to be provided only "conditionally" in the legacy data upload. However, this information is not known by the NCA before the upload. It should be deleted from this document. The same goes for 6.3 package identifier and 5. permanent identifier.	This is only needed in case of updates.
Section 3; Line 226	10	Belgium is not able to specify whether it is a RUP or MRP/DCP, because it is not traced whether the authorisation was given in the first or second wave.	Comment noted.
Section 3; Line 226	10	2.5. Authorisation status; As for the upload of legacy data, only the term ID for valid will need to be provided, we suppose.	Confirmed.
Section 3; Line 226	10	2.9. Source wholesale distributor: This information is not available in our national database nor it is requested in the application for parallel import. It is therefore impossible for Belgium to upload these data.	Comment noted.
Section 3; Line 226	7	Legal basis shall be conditional based on the regulatory entitlement type "Marketing authorisation": "Conformance in chapter 2- <del>Mandatory</del> Conditional"	Rejected - legal basis is mandatory



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	7	Please indicate in the "note application to legacy data", that at least SPC is requested as attached document: "SPC at least for legacy data" SPC is not available in EN in national database but available in CTS.	Comment noted.
Section 3; Line 226	7	(authorised dose form) is mandatory in the chapter 2: "Conformance in chapter 2- Mandatory <del>Conditional</del> (at least one form based on the 4 lists should be provided)"	Change applied.
Section 3; Line 226	7	ATC vet Code is conditional but only described at the product level not the package level: "Conditional ( <del>either at MP level or at Pack</del> )"	Change applied.
Section 3; Line 226	7	The name of product in English is not available in our database. Proposal: this information is available in CTS and could be uploaded in a global export with other data as list of CMSs for instance.	Comment noted.
Section 3; Line 226	7	The information on QQPV is not available in the national database. This information should be provided by MAH: "1.9 Contact (QQPV)- No (mandatory for legacy data)"	In compliance with the Commission Implementing Regulation (EU) 2021/16 and Regulation (EU) 2019/6, it is the responsibility of the NCAs to provide this data.
Section 3; Line 226	7	Pack size as structured data is not available in national database and will not be uploaded for legacy products: "6.2 Pack sizes- (Mandatory for legacy data) No"	The information is required/mandatory to be able to support the submission of the volume of sales by MAHs, and also required to enable automated calculation of tonnes of active sold from sales data for use in ESVAC.
Section 3; Line 226	7	Package identifier is an identifier generated by the system. This identifier can't be provided by NCAs with legacy data: "6.3 Package identifier- (Mandatory for legacy data) No"	This data is conditional, i.e. in initial creation it is conditional and mandatory for updates.
Section 3; Line 226	10	The Target species list is too detailed.	Under review by SPOR team.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	3.3.3. Withdrawal period - note: Belgium can only provide free text. Given the fact that there are three languages in Belgium, do we need to concatenate the NL – FR – ENG text? Or do we need to provide them separately?	Only EN would be sufficient for legacy data.
Section 3; Line 226	10	In the latest implementation guide, it is also foreseen that the ingredient needs to be uploaded. In the RMS list 4.1. 'ingredient role' , not only "excipient" is mentioned, but also "solvent". How is solvent to be understood? Do we need to provide the excipient as part of the product, or also the excipient that is part of the fabrication process but not per definition in the end product? If the solvent needs to be provided too, in practice that would mean that the input of an expert is required which is an additional burden for NCA's and for experts who are already overloaded with work. In the initial upload it should be clear: only the active substance needs to be uploaded. When all excipients and solvents are to be provided at the submission of an initial application this is considered to be extremely time consuming and practically impossible.	Change applied.
Section 3; Line 226	10	4.3.2. Strength quantitative composition; 4.3.3. Reference strength: The number of elements in these two sections that we need to provide has enlarged significantly. It is very hard for us to see how to understand these different elements. We are quite sure we have all the information in our national database, however we are unable to link the fields in our national database to the fields under these two sections.	Chapter 6 on Examples will be published at the end of June 2021.
Section 3; Line 226	10	Can the information regarding the package description be sent to the UPD only in English? Or does it need to be provided for all Belgian languages?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	Can we just give an enumeration of the units of presentations using a separator for 6.6.3 or do we need to repeat all the blocks (6.6.1 to 6.6.3)?	A sample or practical examples regarding 6.6.1. are provided in Chapter 2 and the Chapter 6 on Examples to be published at the end of June 2021.
Section 3; Line 226	10	6.6.4. Ingredient: do we need to repeat ingredients from section 4?	Not mandatory for legacy data.
Section 3; Line 226	5	This section outlines the data elements that fall within the scope of the submission of the legacy data on veterinary medicinal product in UPD. This means, the specified data elements given in the table below are mandatory to provide for all legacy products as relevant depending on product type. And a new table is then also proposed to be added where it is clear which data elements that are mandatory or not depending on product type. This could then also be referred to from the added text as (please refer to table 2 below).	This is already the full list of data elements to be provided; with indication whether they are mandatory or not for the submission of legacy data.
Section 3; Line 226	8	Term UPD ID not defined. Should be permanent identifier.	Change applied.
Section 3; Line 226	3	The same FHIR path is given for two distinct data elements, 2.4 and 2.9. The FHIR path for Responsible Authority is not correct.	Change applied.
Section 3; Line 226	3	The same FHIR path is given for two distinct data elements, 2.13.1 and 2.13.2. This is not possible.	Change applied.
Section 3; Line 226	3	Class 6.1.1 Language: The FHIR path given does not appear to be correct.	Change applied.
Section 3; Line 226	3	Class 1.10 Attached Document: detailed data fields and the references to FHIR data elements suggest a process where the document itself (the contents of the document) is submitted as part of the overall data submission. This is not in line with the previously described process of first uploading the document in order to obtain a UPD ID for it and then submitting the structured product data containing a reference to the document by means of the obtained UPD ID.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	<p>It is not clear to us how we need to understand the upload of the Veterinary medicinal product name.</p> <ul style="list-style-type: none"> <li>• 1.7.2. As we understand it, there will be just one fix ID applicable to all : Full Name (220000000001).</li> <li>• 1.7.3. Country / Languages should be linked to the full name of the product.</li> </ul> <p>Since there are three national languages, this would mean for Belgium:</p> <p>free text full name / 220000000001 / BE – FR  free text full name / 220000000001 / BE – NL  free text full name / 220000000001 / BE – DE</p> <p>However, in our national DB, we do not make the distinction in different languages, when it comes to the VMP product name. FAMHP does not have the active substance name in German.</p>	Change applied.
Section 3; Line 226	5	<p>In the table at the end of the document, the column “Mandatory for legacy data” should be deleted, since the whole table is about mandatory data elements (and all have “yes” in this column).</p> <p>However, for some product type, (i.e. registered homeopathic products, “pet products” and PT), some data elements are not mandatory. This would however be better captured in a separate table 2.</p>	Some data are marked as conditional.
Section 3; Line 226	5	<p>In the table at the end of the document, the column “Conformance in Chapter 2” should be deleted, since it is quite confusing to have this information when taken out of context (Chapter 2 information).</p>	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	5	Proposed change (if any): For clarity, please add Mandatory in front of all comments in Notes column i.e. Mandatory For parallel traded Product only, Mandatory only for batch release sites Mandatory at least given as a free text	Change applied.
Section 3; Line 226	5	It should be clarified which document types that are mandatory for each type of legacy products (preferable in a separate table 2 at the end for stating mandatory data per product type).	This information is provided in Chapter 2.
Section 3; Line 226	8	For legacy data upload the dataset needs to be enriched with CMS country list. For mapping purposes business identifiers will be needed as discussed in the legacy data upload subgroup. Shall we mention this in that guide? Will be needed optionally.	The table mentions mandatory data elements, any other data fields can be provided on a voluntary basis.
Section 3; Line 226	9	Any updates made to Chapter 2 Conformance, FHIR Path or section number/title - need to update and align corresponding entry in Chapter 4.	Change applied.
Section 3; Line 226	9	Ref. 1.3: Chapter 2 conformance is mandatory	Change applied.
Section 3; Line 226	9	Ref. 1.6.2: Chapter 2 - remove comment about at product or package level - n/a	Change applied.
Section 3; Line 226	9	Ref. 1.6.3: FHIR path not correct	Change applied.
Section 3; Line 226	9	Ref. 1.10.1: FHIR path not correct	Change applied.
Section 3; Line 226	9	Ref. 2.4: Not OMS. Now RMS List EU Territorial Authority	Change applied.
Section 3; Line 226	9	Ref. 2.9: wrong Chapter 2 section	Change applied.
Section 3; Line 226	9	Ref. 2.10: wrong Chapter 2 section; plus wrong FHIR path for both 2.10 entries	Change applied.
Section 3; Line 226	9	Ref. 2.11: FHIR path not correct	Change applied.
Section 3; Line 226	9	Ref. 2.12: FHIR path not correct	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	9	Ref. 3.3: If include withdrawalPeriod, FHIR has as mandatory tissue and value	Change applied.
Section 3; Line 226	9	Ref. 6.1.1: FHIR path not correct	Change applied.
Section 3; Line 226	4	Request for addition of an extra field in UPD: Classification if the product is classified as a Controlled Drugs. – YES/NO This is a national decision by each NCA	Rejected - field not included in Commission Implementing Regulation (EU) 2021/16 and thus is not part of the minimum viable product implementation of the UPD. Field can be requested and prioritised for later releases of the UPD, in which case this will lead to updates of the Implementation Guide.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	10	<p>The provided implementation guides have been analysed by FAMHP. We are very alarmed by the workload generated by the addition of data fields in the most recent implementation guide. Compared to our previous estimations on the workload made in the information available last year on this topic, the current scope - and consequently the impact on workload and technical development- has increased substantially.</p> <p>We observed:</p> <p>1/ a substantial increase of data fields, for which there are several we are unable to deliver.</p> <p>2/ we also needed to totally revise our IT-strategy given the required technical development, rules, calculations etc. End of 2020 we have estimated the workload regarding the legacy data upload, based on the 21 data fields. At that time, no development was required. However in the current scope, development is necessary in order to provide the required data (e.g. code 64 in 1.10.6 "Attached document"). It is not just a matter of foreseeing additional budget, we also need to foresee additional resources, we currently do not have, given the fact that we are also working in 2021 on the release of a national database, that will be the basis for the UPD upload.</p> <p>Conclusion:</p> <p>For Belgium the increase of scope regarding the upload of legacy data will make it impossible to deliver the required data within the set timeframe. FAMHP is however able to perform a load based on the first 21 data fields set-up initially.</p>	Comment noted - the IG covers the fields in the Commission Implementing Regulation (EU) 2021/16 agreed by Member States in November 2020. We are implementing what is legally required.
Section 3; Line 226	9	Chapter 2's section numbering changes need to be considered in Chapter 4 too.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Annex I; Line 227	2	Important guidance document missing; OMS Guidance on Assessing Organisation Names and Location Data.	Change applied.
<b>Chapter 5</b>			
Section 1; Line 15ff	2	The vet EU IG Chap 5 appears to be a copy-paste from the human PMS EU IG chapter 6 (apart from a UPD/PMS switch). It is important to remember that IDMP is not a legal requirement for the veterinary sector and only the parts/elements of SPOR that are common to both domains (+ the veterinary-specific data elements) as decided by the veterinary Business stakeholders should be applied to the UPD and related systems.	The text was amended to isolate it from ISO and focus more on UPD.



Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 42ff	10	<p>In the document it is specified that the SPOR API has been built by using FHIR as an overarching standard. This information, together with the details in chapter 2: Format for the electronic submission of veterinary medicinal product information should enable us to prepare the upload of legacy data. However, to FAMHP this information is not concrete and detailed enough to be able to prepare the data upload. Could chapter 5 also foresee information on:</p> <p>1/ How the files will be exchanged. This is according to us insufficiently detailed.</p> <p>We request to provide more concrete details on the data-exchange in chapter 5: Technical specifications.</p> <p>Regarding the format for the initial upload, a technical scheme is missing. In chapter 5, it is stated that a FHIR profile is foreseen but is not yet available. It is unclear to us whether this FHIR profile will only be made available for the definitive data exchange (chapter 2) or if also a separate profile for the initial upload is foreseen. This needs to be clarified.</p> <p>Moreover, for the initial upload, we would like to require a separate XML or JSON scheme. At least we need an example data exchange file (cfr. 2/).</p>	<p>As part of the Informal UAT; and when providing supporting information in our webinars, we discuss release notes and sample files to create products. We also have the release notes available on the EMA website.</p>
Section 3; Line 42ff	10	<p>Concrete example of all the required fields (as well as a pdf in base64), in the expected format/xml.</p> <p>We propose to add a representative example of a legacy data upload file, as we also requested a concrete and detailed example on the data fields to be uploaded (content).</p>	<p>As part of the Informal UAT; and when providing supporting information in our webinars, we discuss release notes and sample files to create products. We also have the release notes available on the EMA website.</p>

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 42ff	10	Clarification on the format of the data upload a) Will it be a large XML file with all the product; or b) One XML file per product (e.g. 400 products equals 400 XML files)	The granularity is to have one medicinal product per file.
Section 3; Line 42ff	10	Large size of the data transfer We also have concerns on the large number of PDF documents that need to be included in the legacy data upload file.	Comment noted - this is out of scope of the guidance provided in this document.
Section 3; Line 42ff	10	Milestones: We would also like more information on the requested deliverables and milestones, or timing linked to it. This would enable FAMHP to anticipate availability of the IT department. Important for FAMHP is to know for example when exactly we need to start testing, when we can start analysing more in detail the FHIR profile and XML or JSON scheme and when we can expect further technical details on the API, UI and file upload interfaces that will be available.	NCA's are invited to join the informal UAT group where more detailed, regular updates are provided.
Section 4; Line 55	2	The following sentence does not take account of differences between the veterinary and human sectors and is written for PMS for human application. The resources as defined in the current API specification offer coverage for the full IDMP model. The overall implementation of the ISO IDMP format and structure shall be done in phases. Therefore, relevant data elements and resources within the overall FHIR model will be enforced within each phase of the development of the UPD	The resources as defined in the current API specification offer coverage for the full IDMP model, as applicable to the human domain. For the purposes of the UPD, only the relevant data elements and resources within the overall FHIR model that apply to the veterinary domain should be used.
Section 4; Line 55	7	Is it possible to provide a FHIR profile describing the structure and content of a whole veterinary medicinal product as requested for UPD? This complete profile could be used by NCA's for a first validation step before the upload of data in the UPD.	Yes, but since this is an implementation deliverable it can only be provided at the same time as the relevant release of UPD.