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 th document a eased for consultation.

Stakeholder no.	Name of organisation or individual
1	Legemiddelverket, Norway
2	AnimalhealthEurope
3	Lægemiddelstyrelsen, Denmark
4	European Group for Generic rinary Product (EGGVP)
5	Läkemedelsverket, Sweden
6	Bundesamt für Ver schutz bensmittelsicherheit, Germany
7	Agence national u médic nt vét rinaire, France
8	Agentur für Ges lheit und ährungssicherheit GmbH, Austria
9	Europea edici Agency
10	Fede Agentscha eneesmiddelen en Gezondheidsproducten, Belgium
11	Jav age ublike Slovenije za zdravila in medicinske pripomočke, Slov

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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 significant differences between the human and veterinary domain (e. g. in the relevant data fields). Therefore it is 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 contain all four identifying parts: "Vet" "EU" "UPD" and "Implementation Guide" / "IG" in order to clarify the scope and support identification of other possible VMP-Reg related implementation guides.	Change applied.
3	Chapter 6: product examples 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	We are missing a definition of a medicinal product which is a combination of name, strength and pharmaceutical form. 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. Do we correctly understand that the FHIR resource id provided in the UPD is the same as the permanent identifier for the medicinal product?	The name must not be part of the identifer as it can change as this differs between different countries. Yes the permanent ID and product ID are stable. About the FHIR resource id, yes the permanent identifier is the FHIR id for the medicinal product.

2. Specific comments on text

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Introduction			
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 3rd country product names by January 22 - how is it achievable? MAH are very concerned that there will not be enough time between decisions on key issues (e.g. Feedback Item), upload of legacy data & provision of test environment 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	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 '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 be available in a variation application? Or even provide all mandatory data for products where a MAH 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 agreement 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
Chapter 1			
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 to be 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 system 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 description of prerequisite steps and processes to be undertaken by NCAs and MAH	Change applied.
Chapter 2			
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 = Re…hen… state, in text (line 671) 2.10= destination wholes… distributo… and following sections	Corrected.
Glossary; Line 143	6	RUP is now SRP, please check for consisten… …ou… …ut the document	Change applied.
Scope; Line 160	5	New abbreviation is agreed in CMDv (and include… …S list; please change throughout do… …nt.	Change applied.
Scope; Line 163	5	To better reflect homeopathic and pe… …ducts	Change applied.
Scope; Line 173	7	Chapter 2 mainly focuses … …rised … … parallel trade products. Data fields r… …ested … …ch ty… …of products should be identified and clari… .	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 n… …eeded, t… …cts are not VMPs so clearly not in sco…	Section retained so it is clear what is not in scope.
Identification of a VMP; Line 196	5	It is impo… …se… the different levels of datasets as an int… …ction.	Change applied.
Identification of a VMP; Line 197	5	…ou… …e good t… …learer	Change applied.
Identification of a VMP; Line 207	5	…less c… in this context	Text amended.
Identification of a VMP; Line 212	5	To be… …ry 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 numbers as 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	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 change of procedure number (e.g. RMS transfer or corrections).	This is confirmed.
Identification of a VMP; Line 225	5	It is of any use to have the full procedure number here, i.e. if it was an MRP or a RUP/SRP that was the first procedure, they ended up in having one MRP product that will have that procedure 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	Out
Identification of a VMP; Lines 231-252	5	The version control is very strange for a "stable" ID. It n[illegible] be better described, e.g. that the complete product d[illegible]aset will be given different versions during the lifecycle, bu[illegible]e ID will still stay the same (be stable).	This is corr[illegible]ct, we have reviewed the text on [illegible]sioning, which is in fact described in the SPOR A[illegible] more general user documentation.
Identification of a VMP; Line 231-235	3	It seems to us that a phrase like "the same Prod[illegible] is sometimes used to refer to the entire entity/data se[illegible]nti[illegible] by the "Product ID" rather than to th[illegible]ata element "P[illegible]ct ID". E.g. in the text of lines 231-23[illegible] it is not [illegible] wh[illegible]the exact meaning of the following i[illegible]... w[illegible]erate[illegible]w version of the Product ID…". If the identifier, the Prod[illegible]ID, is the [illegible]me, what does a new version imply? Please be ver[illegible]xplicit in the [illegible]ncerning the intended meaning of w[illegible]ds li[illegible]nd "product".	Change applied throughout document.
Identification of a VMP; Line 236	8	Sometimes a[illegible]ants [illegible]have a separate Marketing Auth[illegible]on for a new[illegible]get species that is added in the l[illegible]ycle [illegible]decis[illegible]o include the new target species in the [illegible] or [illegible]in a new one lies with the MAH. So this should not [illegible]n au[illegible]matism in the system. The Competent Authority should [illegible]somewhat of a control whether a new product is [illegible]ated 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	[illegible] paragraph is confusing because it mentions attributes (e.g. [illegible]me) 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	Ou[illegible]ne
Identification of a VMP; Line 253	1	Level 2 Permanent identifier: Is Permanent identifier the sam[illegible] as PMS ID? Proposed change (if any): Align with IG for human use	Change[illegible]
Identification of a VMP; Line 253	8	We propose to clearly state that this permanent ide[illegible]er is the unique identifier to clearly identify a definite me[illegible]al pr[illegible]uct in the UPD. We also think that the naming conve[illegible] confusing between level 1 and level 2.	[illegible] 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 10000[illegible]004); only the term given above to be used	Change applied.
Identification of a VMP; Line 257	5	Change/add text for clarific[illegible] [...] authorised in several [illegible]mber S[illegible] from the same MRP/DCP or SRP are sep[illegible]ely identi[illegible] [...]	Change applied.
Identification of a VMP; Line 261	5	Proposed change (i[illegible]ny): [illegible](level [illegible]or clarification in the bullet point - Product ID [illegible]vel 1)	Change applied.
Identification of a VMP; Line 263	8	MAH cannot L[illegible]acte[illegible]ic because it would make identifier unsta[illegible]	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	[illegible] w[illegible] not understand what a "new version" of a per[illegible]ent id[illegible]fier means and how this will be technically [illegible]ealise[illegible]oning of permanent identifiers will increase the [illegible]hnical [illegible]ort and is in principle the same as you would define a[illegible]w identifier. W[illegible]recommend that the permanent identifier will not change [illegible]uring the lifecycle of the product.	Corresponding text changed in order to reflect that the versioning applies to the product and not to its identifier.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 version control which is in fact also described in the SPOR API and more general user documentation.
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, you mean a versioning of the data behind the identifier	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 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 Identifiers (level 2) for PCAPs, one for the EU and one each for NO, IS and LI	Change applied.
Identification of a VMP; Line 289	7	In the case representing the UPD IDs, the second product ID (level 2) 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.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 [illegible] has been updated accordingly, and [illegible] packages are [illegible] represented on each of the products [illegible] their national dataset.
Identification of a VMP; Line 290	2	Figure 1 on UPD Product Identifiers should depict the situat[illegible] of Product IDs and Permanent IDs per procedure type. It is AnimalhealthEurope's understanding of the following - CAPs: 1 Product ID + 4 Permanent IDs (EU, IC[illegible]NO) - NAPs in an MRP/DCP/RUP: 1 Product ID + n Per[illegible]IDs (n = number of MS involved as either RMS or CMS - NAPs authorized by NP: 1 Product ID [illegible]1 Permanent [illegible] country	Change appl[illegible].
User Guide; Lines 304-305	5	Add some word in both lines: [...] electronic submission of [illegible]medi[illegible]oduct data and documents into the UP[illegible]	Change applied.
User guide; Line 308	5	Please, add the below text[illegible] The FHIR message i[illegible]ased [illegible]he IDM [illegible]tandards for human medicines with [illegible]able modif[illegible]or veterinary products and the UPD.	Change applied.
User guide; Line 310	7	In the descript[illegible]e re[illegible]rement "Repeatable", an explan[illegible]on the class c[illegible]d be useful: "A class could be re[illegible]abl[illegible]ith repe[illegible]e or not individual data fields. A c[illegible]ete[illegible]t d[illegible]ta fields is repeated in this case"	Change applied.
User guide; Line 310	7	In th[illegible]scripti[illegible]of the requirement "Conformance", an explana[illegible]the class could be useful: "a class could be [illegible]itiona[illegible]nd data fields belonging to the class could be m[illegible]atory. Once the conditions for the class are fulfilled, all m[illegible]datary data fields shall be fulfilled. If the conditions are not [illegible]lled, 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 require[illegible] implement the ISO IDMP standards. ISO Path- The mapping of the ISO IDMP technical [illegible]ifica[illegible]s.	Since [illegible] no requirement to align with ISO [illegible] have j[illegible]etai[illegible] in the documentation the [illegible]apping to t[illegible]IR path which is now in line with [illegible]G for human use.
User guide; Line 310	9	The links to "FHIR resource" list are to R5 Preview 3. [illegible] expecting this to be linked to R5 Preview 2.	[illegible]hange applied.
User guide; Line 310	5	Clarify in the introduction FHIR/IDMP as [illegible]osed for line [illegible] and then delete here. Proposed change (if any): Please [illegible] text [illegible] And mapping to ISO IDMP sta[illegible]rds Note: for the implementatio[illegible] the UPD[illegible] not required to implement the ISO IDMP sta[illegible]rds.	Change applied.
User Guide; Lines 316-317	2	"Terms in RMS shal[illegible] accept[illegible] [illegible]status, unless specified otherwi[illegible] Comment: this s[illegible]n[illegible]ported, since the go live of the UPD should not bl[illegible] any [illegible]y 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 [illegible] shall only b[illegible]ccepted under CURRENT status for the [illegible]ation [illegible]pro[illegible]cts. "Ter[illegible]S sh[illegible]e accepted with any CURRENT status, [illegible]nless [illegible]fied [illegible]erwise"	Change applied.
User guide; Line 317	5	[illegible]nform[illegible] about new RMS terms as needed. If n[illegible]ed, new terms can be requested via the SPOR portal.	Change applied.
User guide; Line 318	8	Is th[illegible]election 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? 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 to be link to R5 Preview 2.	Change applied.
User guide; Line 338	1	Figure 2 on page 12: The physical part 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 updates in 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 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 the relevant part of the FHIR standard, but rather to the 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: http://build.fhir.org/resourcelist.html Add: (section Medicati 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 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 I 0000005003); only terms listed above to be used	Change applied.
Section 1.2; Line 362	7	Product status: describe the of an of the authorisation status on product tus. · Provisional: initial pro t state ap able to products approved under DCP/M UP proce re, but not yet authorised in individ State. The "PROVISION " prod status is linked to the authorisation status "PEN · Cur t: Initial status the following products when they are s to the UP AP, NAP, registered homeopathic oduc ucts allowed to be used in a member State in nce Article 5(6) of Regulation (EU) 2019/6 and pa tra products. The product status 'CURRENT" remains f the orisation status change to "valid", or "suspended" Non-current : status applicable to any product with an thorisation status changed to "revoked" or "withdrawn" Nullified: status applicable to any product that is deleted by a user	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 (200000005006), 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 has to be updated in the Chapter 4 for consistency. Also 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.combinedPharmaceuticalDoseFo… Not repeatable although there is a business need to hav… attribute repeatable. In the H domain they have a di…rent mapping for it.	Change…
Section 1.3; Line 365	9	Proposal to use FHIR extension which allows f… ultip… alues.	Change applied.
Section 1.3; Line 371	8	As already mentioned in a discussion between CMD… …M: We have a product with 2 pharmac…al forms: Mite… drops and cutaneous suspension for d… and cats. We applied for a combined term at EDQM but it was …ed… hat 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 secon… last line… see section 5.4…) please change to "Secti… 4"	Change applied.
Section 1.4; Line 373	7	Comment: the l… statu… the s…ply is not repeatable. However, it …uld be repeata… for MRP/DCP/SRP/NAP. Proposed ch…ge … …es" 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	Se… …ference to F… …s not correct in "User Guidance"	Change applied.
Section 1.4; Line 373	9	…ctor… …tements. Says if at package level to be blank at …uct l…l. Then this has been added in red "The term Veter… …edicinal product subject to veterinary prescription …cept for some pack sizes will then be shown at the product …el."	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Ou me
Section 1.4; Line 373	5	Please add text The legal status of supply is usually defined at UPD produ l 2 and should be specified as Veterinary Medicinal prod ot subject to veterinary prescription or Veterinary me nal product subject to veterinary prescription. And also add text at the end for clarification: The term Veterinary medicinal product subject t rinary prescription except for some pack sizes will then b w the product level. Further detailed status of supply cou relevant future versions of the UPD.	Cha ppli
Section 1.4; Line 373	9	Legal status of supply' to cha for 'L status for the supply' based on UPD I ementing , RMS list, etc.	Change applied.
Section 1.4; Line 373	9	MedicinalProductDefinit egalStatu fSupply Can it be differ r co for ?	Change applied.
Section 1.5; Line 377	5	Probably it uld not be possi to report on "a group of countries", l . Proposed ch (if any D or a group countries (in two places in the text)	Change applied.
Section 1.5; Line 377	5	me te Dat rovided" should always be set when the is c ed in the UPD, since this information is at that ti t y rovided by the MAH. This would also be the case for th ucts uploaded as the initial input to the UPD where e MAH also needs to add this data for each product. ~~nce this information is to be provided by the MAH, at the eation 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"."~~	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcom
Section 1.5; Line 377	5	Change the term given: date for "~~not marketed~~ No data provided")	Cha ied.
Section 1.5; Line 377	9	I understand that it has been decided that Availability statu be at Package level and not product level. Therefore, this section will be moved to be within section 6 Package edicinal product	Change ap .
Section 1.5; Line 384	6	How is it controlled that the MAH fills in data in fiel t is mandatory but is there a red flag if not changed by 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 r guidance of .2. Availability status (see comment also fo 390 b) and would be better to stay only t be d the introduction. Proposed change (if any) lete the f wing text: Since this information is t provide the MAH, at the creation of the v inary m duct following initial marketing aut isatio proval by the NCAs, this information is not known ability status shall be specified with the value Data P ded".	Change applied.
Section 1.5; Lines 386 and 390	2	The o Data Pro d' was intended for use in legacy data rodu orised before Jan 22. Such products may be, o t be arketed. As the case refers to the creation of a new p ct CA after application but before authorisation it ows t cannot legally be on the market. Therefore 'Not eted' 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 fi… Country should not be repeatable. All the class is repeatable, at each time country, a… status and availability state date together. - re…eatable fo… Country No	…nge …ied.
Section 1.5.1; Line 387	9	Repeatable should be No. Only 1 countr… be …uded within each marketingStatus entry in FHIR. See http://hl7.org/fhir/2020May/marketingstatus…l#M…ketingStatus	Change applied.
Section 1.5.1; Line 387	2	Need a value "Non-EEA country … sales dat… reporting.	SPOR team informed
Section 1.5.1; Line 387	5	Propose to use nati… da… instea… national entitlement everywhere in the …cument, …e it is easier to understand. Proposed change (…ny): the nation… ~~titler~~ datas…	Change applied.
Section 1.5.1; Line 389	2	Will th… rm name or t… ort name will be used?	Change applied (short name to be used).
Section 1.5.2; Line 390	6	Will the … perio… r the term "temporarily unavailable" be …rly defined a… where? When exactly will MAHs be required to … th… tatus to "temporarily unavailable"? …pos… change (if any): …lease …rify what is meant here to avoid confusion. …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.	Cr[illegible]pplied
Section 1.5.3; Lines 394-395	6	Table under 1.5.3 "…the availability status date is mandatory to be provi[illegible]." Includes this sentence that an entry cannot be fini[illegible] without entering the actual date? How will be guarante[illegible]hat t[illegible] entries by the MAH as asked for in 2019/6 Ar[illegible]2[illegible] (vii) will be up-to-date and changes will be entered i[illegible]nely manner?	The info[illegible]tion 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[illegible] Availab[illegible]date "…The first [illegible]ue will [illegible]created by the system, at the time of initial entry [illegible]into the UPD (date for "not mark[illegible]ed"). [illegible]But in li[illegible]s 384 to 386 is says "Since this i[illegible]on is to be [illegible]vided by the MAH, at the creation of the [illegible]teri[illegible]dicinal product following initial marketing [illegible]satio[illegible]pproval by the NCAs, this information is not kn[illegible]vet[illegible] the availability status shall be specified with the [illegible]value[illegible]Data Provided". [illegible]us, it sounds as if the first entry will be done by NCAs or the [illegible]ency, 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 Regulation (EU) 2019/6) Please delete example generic with old legal basis ((Article 3 (1) 2001/82/EC	Change applied.
Section 1.6.1; Line 398	7	Legal basis: as described, legal basis already 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 life cycle of specific products. For instance for limited market and exceptional circumstances where they will be required 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 "Marketing Authorisation Application Legal Basis" (in PMS). In lower environments the list name is "Application legal basis". They don't contain the new values for UPD. Are you working 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	T[illegible] FHI[illegible] for A[illegible] Vet Code of [illegible]edicinalP[illegible]t[illegible]nition.productClassification is [illegible]rect. FHIR [illegible]ment 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" 10000011[illegible]49 · ATC vet code is not applicable for Authorised and [illegible]d veterinary homeopathic medicinal products.	C[illegible]e applied.
Section 1.6.2; Line 402	9	If product is not "Registered veterinary homeopathic med[illegible] product" is it mandatory to have either a[illegible]e specified or 1.6.3 ATC Vet Code flag set?	Change applied.
Section 1.6.2; Line 402	5	Concerning the text: "The ATC [illegible]t app[illegible]o Registered veterinary homeo[illegible]nic me[illegible]l products, should the value for this veterinary [illegible]dicinal pr[illegible]ct be specified, the value must be set to 'F[illegible]lse'." - Who would set th[illegible]lag? Coul[illegible] automatically to 'false' for this product t[illegible]e?	Change applied.
Section 1.6.2; Line 402	9	Vet EU IG: "If A[illegible]e is[illegible]t available because not yet assigned [illegible]he ATCvet Cod[illegible]st maintenance organisation and not v[illegible]va[illegible]le in RMS[illegible] field should be left empty but inf[illegible]tion [illegible]availability must be provided in the ATC Vet C[illegible]g (i.e[illegible] least one of ATC vet code OR the ATC Vet [illegible]de flag [illegible]t[illegible] provided if applicable)." Is [illegible]ossibl[illegible] scenario where the product has 3 ATC Vet cod[illegible]nd two of them are pending? In this case the user will have [illegible]pending flags and 1 correct ATC Vet Code. To confirm if it[illegible]ossible.	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	change. ATC 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 true or false. Will there be an info button in the UI or different	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 [...] 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 in the UPD is mandatory or optional.	This is a procedural business process to be established - cannot be mandated technically.
Section 1.7; Line 429	5	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	Outc
Section 1.7; Lines 429-430	2	It should be clarified in which characters and language additional veterinary medicinal product names as applicable t third countries shall be specified. Would Cyrillic or Japane characters be acceptable, or should it be Latin charact rs? Should it be the veterinary medicinal product nam ocal language (and possibly Latin characters) or the lish translation?	chang plied
Section 1.7; Lines 429-430	2	Confirmation is sought that additional veterinary me al product names as applicable to third c ntries shall no specified at country/language level, si ntered as lternative names within the common/European data In c of products approved in multi Memb tes per national procedure, the th countrie oduct names should not be requested multiple nes.	Comment noted.
Section 1.7; Lines 429-430	2	It is assumed the rina edicina oduct names as applicable to th countries w e part of the information accessible to ge lic.	Confirmed, to be clarified in Access Policy.
Section 1.7.1; Line 432	1	In the Tag Us ince: "The terinary medi al product name (invented name, st gth, ace form)," missing "Dose" as in p na tic ose form? Pro d cha (if any): dd "d the text.	Change applied.
Section 1.7.1; Line 432	6	es: Special characters: it might need to exclude the special c acter "trade mark" which is not allowed to use in VMP n e.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outc
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.	hange app
Section 1.7.2; Line 435	6	'ID' should be written in capital letters. Furthermore, if only the value '220000000000 ID the term 'Full name' shall be inclu ction 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 vaccin ame for C - does this mean populate FULL NAME a N Part fo cientific; or just one name in fullname th scientific pe term ID. As Value says must use f nam nly affects EMA	Change applied.
Section 1.7.2; Line 435	9	The guide needs y th for vaccines the scientific name part wil to be provide for this name the user will need to p de t ter 220000000003	Change applied.
Section 1.7.3; Line 436	9	Cla ic eed be added to the guide related to how the country lang ge will be captured for CAP products.	Change applied.
Section 1.7.3; Lines 439-441	3	ated, ta structure that is repeatable is the medicinal pr f nam class. Thus, the final sentence in this paragraph is misl ing.	Change applied.
Section 1.7.3; Line 440	9	It is t country/language class that should be repeated, but entire "name" class.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	[illegible]com
Section 1.7.3.1; Line 443	8	Why do the CMSs have to choose the country? For MRP/D[illegible] products the RMS creates the products at End of Proc[illegible]e all CMSs, doesn't it? So the country is already ther[illegible]	No, t[illegible]s have to create their own national datasets, and add their national translations with the applicable country. RMS will only provide the [illegible]oduct name in English.
Section 1.7.3.1; Line 443	9	Values - Is any validation to be applied if th[illegible]ue i[illegible]t selected from the RMS Country list? Is any re[illegible] to an[illegible] other list to be accepted?	Change applied.
Section 1.7.3.1; Line 443	9	Clarification needed: what is expe[illegible]d in country fo[illegible]s products? Are we expecting the na[illegible]24 langu[illegible]ges? Can we provide examples please fo[illegible]Rs? Is t[illegible]ou[illegible] for the EN name 'EU' or a country [illegible]the n[illegible] language?	Change applied.
Section 1.7.3.2; Line 446	9	Section numbers for 1[illegible]3.1 and 1[illegible].2 need to be corrected as parent section is now [illegible]3	Change applied.
Section 1.8; Line 449	7	A link betwee[illegible]PSM[illegible]the[illegible]H 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	Delete most of the text in the last bullet point to keep it cle (as assumed to be meant) The unique pharmacovigilance master file location information should be submitted to the database as follows: 1) The PSMF reference number (code) as assi d by QPPV. 2) The PSMF location stated as a LOC ID linke organisation listed in OMS. Change the headings to m it in line with normally used wordings/abbreviations. I rms are not important to keep strict in t adings for the vet IG. Propose to Change the Headings to: (Pharmacovigilance Syste file (PSMF) File type (PSMF) File code (PSMF) File locati Pharmacovig ce Contac (QPPV) Ide ier (QPPV) Loc	Chang d.
Section 1.8; Line 449	9	Co tes mandatory tribute according to FHIR. cur tRefere atus cu ence.content entR ence.content.attachment and his is e mapping for 1.8.3 (PSM) File location cumentReference.custodian	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	PSMF location reference number 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 numb coded below under 1.8.2. (PSM) File code Another question: It is stated in (1) At the time of the marketing au isati application, the applicant should submit electronica PSMF location reference number (…). Is this meant as an en th eAF? Or a separate entry in a field in th PD additional e eAF? Or could this be stated on a docume loaded with the dossier via CESP for example? Thi ould a a ectronic submission. If this location is a new one hen the C entry has to be amended/updated first bef his PSMF ation reference number can be ge d ar ered	Clari rovide
Section 1.8.2; Lines 463-464	6	Value: string….a ee text inserti y by error prone, perhaps a standardised ma e better.	Rejected.
Section 1.8.3; Line 465	9	Table is not com and h no FHIR path	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 1.8ff.; Lines 465ff.	6	Comment to 1.8 and 1.9: Additional PSMF data and QPPV (Summary of the PSMF) 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 ca changes (VNRA) occur this must be updated in the D. Proposed change (if any): Therefore, fields are ne information from PSMF Summary. E.g. for the record management system a field where the "name of the da used" can be entered, e.g. as a RMS lis y(?) or the ty of system at least (e.g. database, Excel, MS , etc d in case of a commercial database field name of the database (as string valu r coda a RM st). 1.9. Contact (QPPV) -> rel topic: C ges in the Summary of PSMF Proposed change ny): Ad oad up the "statement" between QPPV MAH asked for in the "Summary of the PSMF" and sho able to be updated in the UPD for notifi ion wh chang n the summary of the PSMF occu	Info ion in PSMF (incl. PSMF summary) no ded in PD. Any such changes must be manag ere.
Section 1.9; Line 466	6	C ent: uired data here is very sparse. Will more data field ded e (i.e. contact information, what about mail/ e/ mobile contact data?)? We have manual t to p ue the required data and a finalisation of the re ed information is necessary before we can perform this wo F our understanding these will be the information that will be used in case of trying to contact the QPPV.	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 domain.	FHIR was 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 [illegible] path	Change applied.
Section 1.9.3; Line 473	6	Contact details, are these only postal address and country? What about email/ phone/fax/ [illegible] contact data? These would be the ones that will be used in case of trying to contact QPP	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	The "general" table here mentioning information as for other data should be added to clarify if the attached [illegible] as repeatable, mandatory, etc.	Change applied.
Section 1.10; Line 474	8	Is it 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.	Ch[illegible]e applied
Section 1.10; Lines 474ff.	3	It would seem that the data model lacks an element fo[illegible] 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 lang[illegible] for Germany and SPC in German Language for Austria.	Change applied.
Section 1.10; Line 475	5	Important to state it is the public ve[illegible]he AR	Change applied.
Section 1.10; Lines 477-481	2	For products approved by MRP/D[illegible]/RUP, and [illegible]case English is an official language in non[illegible]f th[illegible]mber St[illegible]s involved in the procedure, will the [illegible]glish vers[illegible]roduct information (SPC/PL/[illegible]B) ag[illegible]t the end of the procedure attached by the RMS [illegible]ommon/European data set remain visible [illegible]the ge[illegible]eral pub[illegible]once all Member States have ente[illegible]national t[illegible]ations? We bel[illegible]this [illegible]helpful to the general public.	Data publication is out of scope of this guidance.
Section 1.10.1; Line 493	9	User Guid[illegible]"The [illegible]assigned to the document once it is [illegible]ded to [illegible]PD[illegible]ystem must be specified. " This [illegible]ment [illegible]icts with Values row where it states that this identifie[illegible]assigned by the system. Therefore, not attribute expect t[illegible]opulate 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 ~~once it is uploaded to the UPD system must be specified. Th~~ ~~identifier~~ is specific to this specific version of the docum . Any new versions will get a new ID. This unique ID…	Chang .
Section 1.10.1; Line 493	5	Changed for more clarifying text (as assumed): The status of this document must be specified as a based on the following values: - "current": This is the current ~~reference~~ version of this document. superseded": This version of ha en supe ded by another version. - "entered in error": This vers was ed in . Add after the link: ;only the ms state ove to be used	Change applied.
Section 1.10.2; Line 494	3	We can see the need for the us "supe ded" in the UPD, but would this statu natu be th esult of a submission of a new version the "same" do ent (identical product/type/co y/ ? It seems unneces to req both submission of the new versio bmission of additional "Attached document" data uctu der mark the superseded document as supe	Change applied.
Section 1.10.2; Line 494	2	"Entere not essarily an intuitive term for a reference ed in	The value has been renamed to 'entered-in-error'.
Section 1.10.2; Line 494	6	"E d" is misleading Does is mean that wrongly uploaded documents cannot be del d? posed 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 should 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). 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 100000155552) listed in Product Information Document Type (RMS list ID 100000155531)	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 this 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 mentioned 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	Overall terminology 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 app
Section 1.10.3; Line 495	5	Add the terms now available and additional terms that 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.	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 th of documents in relation to language (v combination) as this is expected t fully mmon SPCs for countries within an MRP P/RUP th hare common languages. In addition, it will alig current ctice for CAPs, for which only one versi each equired.	Change applied.
Section 1.10.5; Line 497	9	Value: it is not an RM st as it ot allowed here by FHIR. Must be: One of the in the EU in the list of languages BCP-47.	Change applied.
Section 1.10.6; Line 500	5	The ISO El me and P hould be Content icina /AttachedDocument/Content	Change applied.
Section 1.10.7; Line 501	2	It is ques wheth document title is needed since a d ent ty alr y available. yes, docu title could be computed based on docume pe and product name in English. Please no hat the abbreviation "SmPC" is more used in man rma and for historical reasons. A decision on the use o 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 expe... i.e. a specified name or the file name to appear (like the examples).	Change a...
Section 1.10.8; Line 504	6	References to the Product ID or Permanent ID that t... document covers should be specified, as applicab... Mean... as applicable" that in case of documents related not ... VMP but to the MAH in general for example, these referen... lo n... apply? Otherwise it will be difficult to lo... up e.g. the Q... statement, summaries of inspection rep... as inspection outcomes when the inspection was not pro... rela... etc.	As ...icable, 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 ... nt ca... e reference to Product ID? I thought D... mentRe... ce wi... only linked to Permanent ID i.e. to Medi... ProductD... ition/id	Change applied.
Section 1.11; Line 507	2	The inclusion of pa... trad... roduct... not clearly defined	Change applied.
Section 1.11; Line 508	9	Reword first s... enc... his class enables to cross-reference one ... vete... ary medicinal products as avail... o the UPD."	Change applied.
Section 1.11; Line 515	9	Th... erms ... here... n't exist in lower environments and are o... P... D. Plus ... e re... term id in PROD 200000013183 as has ...scripti... ormed Consent (Article 21 of Regulation (EU) ...6)". ...oesn't include the word "application" which is in... ed 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 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 the legal basis is…1.6.1 for Par Trade there only regulatory entitlement, Change: reference to section 1 (see line 8)	Change applied.
Section 1.11.1; Line 530	9	Term 200000016179 "parallel trade of" does 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 part of User Guidance is not quite correct – what needs to be selected is the type of the cross-reference (relationship) and 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" referred to in article 102 of Regulation 2019/6", then parallel trade 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.productReference 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 should 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 Path and example	The FHIR Path for Reference product identifier of MedicinalProductDefinition.crossReference.productReference 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	"….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. "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" 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 will have variations 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 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 handling technical groupings in a consistent way when both old and new products are involved, since some would have the manufacturers and others not.	As stated in chapter 1, for legacy data only batch release manufacturers is required.
Section 1.12; Line 543	7	We need a section "1.12.3 Note" with free text. Indeed, we want to specify for instance which site is responsible for which packaging of the VMP. Ex : site A is responsible for packaging, site B is responsible for blisters… This "note" should be optional and detailed the manufacturing activities as described in the eAF.	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 Manufactuing Business Operation may be undertaken by at most one Manufacturer Establishment". Therefore, Repeatabl should be no.	Cha ppli
Section 1.12.1; Line 548	9	Repeatability is not supported by the PDM, so the whol ass must be repeated and not the manufacturer.	Ch applied.
Section 1.12.2; Line 549	9	There is confusion about which term ID should be indicate the Manufacturing activity for Batch release (mum data requested for legacy data).	Change applied.
Section 1.12.2; Line 561	9	Repeatable is not correct. FHIR only sup one type.	Change applied.
Section 1.12.2; Line 564	7	In the section examples, the v ufactu tive substance" should be delete s we wi store this information in the UPD curr y and the ample "Batch certification" could be dded "Example(s): Processing oper ons fo medicinal product (100000160413 ol testing of medicinal product (100000 408), ~~Manufact of active substance (100 67).~~ Prim ackaging (100000160463), M ctu nsible for batch certification (100 0407)	Change applied.
Section 2; Line 566	9	uld w class for the entitlement in this section ting is mandatory and repeatable? Similar to other sec s in the document.	Change applied.
Section 2; Line 584	4	"If egistration for a homeopathic veterinary medicinal product anted, 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).	Chang[illegible]plied.
Section 2; Line 599	5	Added text for clarification [...] a wholesale distributor. (Please note, the MAH of the [illegible]urce product is still responsible for the product even if it is [illegible]istered for parallel trade in another destination country.)	[illegible]ge applied.
Section 2.1; Line 607	9	Do the 'veterinary medicinal products allowed to be u[illegible] a Member State in accordance with Article 5(6) of Regulati[illegible] 2019/6 or exempted from the provisions [illegible]rticles 5 to 8 o[illegible] Directive 2001/82/EC in accordance with A[illegible]4(2) of [illegible]e same Directive' have entitlement [illegible]alue 'i[illegible]ti[illegible] authorisation' always? - Are the examples the only [illegible]es applic[illegible] to this field?	[illegible]e 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 w[illegible] the RMS [illegible] of the terms provided: "Example(s): Marketing autho[illegible]i[illegible]000061), Homeopathic registration (2000[illegible]5756), [illegible]arallel Trade Authorisation (22000[illegible]3), Veterina[illegible]edicinal products intended for ani[illegible]excl[illegible]kep[illegible]s pets (200000016178)"	Change applied.
Section 2.1; Line 614	9	Can [illegible]n the [illegible]amples the following value: Veterinary medicin[illegible]du[illegible]ntended for animals exclusively kept as [illegible]	Change applied.
Section 2.2; Line 615	9	Onl[illegible]e MA number (the current one) can be referenced in this data[illegible]ment. Any change of an MA number triggered by, for inst[illegible]e, a transfer of MAH e.g. in Ireland should be recorded [illegible] 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.	Cha[illegible] appl[illegible]
Section 2.2; Line 615	9	FHIR Element Name - should corrected to last element in FHI[illegible] Path.	Chang[illegible]plied.
Section 2.2; Line 618	4	This sentence seems to be incomplete: "If the MA nu[illegible] was assigned by the EU Commission, then the MA number a[illegible] in SPC"	Change applied.
Section 2.2; Lines 621-622	4	To be noted: Not all NCA will fill the MA nu[illegible] in the SPC, b[illegible] there is a certificate with the MA number.	Noted.
Section 2.2; Lines 621-628	5	To delete irrelevant wordings (probab[illegible]pied f[illegible]he[illegible]han IG, related to art 57) and also mi[illegible]cha[illegible]	Change applied.
Section 2.2; Line 624	8	A transfer of a MA to a new MA [illegible]ally does[illegible]hange the MA number. MA numbers don't hav[illegible]rsions at[illegible]n AT.	Noted, you will always use the latest verison of the product ID.
Section 2.2; Line 635	5	Change the text a bit: ~~This section could al[illegible]contain~~ For products that a[illegible]t[illegible]d medicinal products, this section should be use[illegible]	Change applied.
Section 2.2; Line 640	5	It would b[illegible]h with just [illegible]ping the first sentence in the User g[illegible]nce, [illegible]e th[illegible]e bullet points under are just a repetitio[illegible]t giv[illegible]bove.	Rejected.
Section 2.2; Line 641	8	S[illegible] above.[illegible]ast[illegible] MRP/DCP and NAPs the MA numbers are [illegible]ende[illegible]	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: 123456/2016, 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 update products via PLI based on a separate permanent identifier.	Confirmed.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Out
Section 2.3; Line 656	9	Is the country grouping expected for all values related t country or it doesn't need to be provided by the use e.g. 2.3. was required in July and not anymore). Can the guide specify which values could be s ed h e user in each one of the 'Country' fields (we need er by Country grouping for example)? The section 2.13.3 Procedure type - thorised' DCP| RUP and NAP products, states that 'The au sation co ntry must have been specified as one of th EEA co ies ection 2.3 "Country". In RMS we have 3 differ EEA cou grouping: European Economic Area - EEA | E excluding (NI) |EEA and UK(GB) which one appli e? e spe that in the guide? For CAP prod other rules with respect to country 'EU' or 'LI'/'NO'/ Do we need ol th alues that in country must be pro (in all sectio So must be 'EU' the country for CAPs .3? th	Change applied.
Section 2.4; Line 659	6	th ta 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 (org tion) 2.10. Destination wholesale distributor (isation) 2.11. Reference member state 2.12. Concerned Member s es	Noted.
Section 2.4; Line 659	5	Add ISO references ISO Element name: Identi ISO Path: /MedicinalProd t/Mark gAuth isation/Organisation(Medicin esRegulatory/ er	Change applied.
Section 2.4; Line 659	9	Why is it a refer e to an MS list in which terms denote org s without a mapping to the corresponding isat MS? Is that common with H domain?	Change applied.
Section 2.4; Line 659	9	FH ent e - 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	The impact of the change of the authorisation status throughout the lifecycle of the product on the Product status 1.2 shall be described: "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" "Withdrawn" has a product status "NON-CURRENT"."	Information related to the statuses that a product can have throughout its lifecycle is described in the section 1.2 Product Record Status. A product in UPD can have the statuses current, provisional and nullified, therefore non-current has been removed from the IG. 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.
Section 2.5; Line 660	5	Propose to set a term for the authorisation status during the period of End-of-procedure and Authorisation, this can be done automatically when the RMS creates the product.	Change applied.
Section 2.5; Line 661	7	Example(s): Valid (100000072099), ~~Expired (100000072100),~~ Revoked (100000072121), Withdrawn (100000072113), Pending (220000000066), Suspended (100000072122)	Change applied.
Section 2.8; Line 665	7	The excel file "change line" 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 the "Not applicable for parallel traded veterinary medicinal product.". Conformance is still Mandatory. "605-Update ". (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.	Cha[illegible] app[illegible]
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 [illegible]ld b[illegible] specified as both Product owner and Destination wholes[illegible] distributor. This seems unnecessary.	Rejec[illegible] the product owner remains the MAH whilst t[illegible]mpany holding approval for parallel trade is the destination wholesale distributor. (See C[illegible]mmission Implementing Regulation (EU) [illegible]21/16)
Section 2.9; Line 668	9	User guidance and Conformance have differ[illegible] criteria as to when this applies. One is based on legal bas[illegible]l one on the authorisation/registration/entitlement type. Exp[illegible]d th[illegible] would be referring to the same da[illegible]	Change applied.
Section 2.9; Line 670	6	Please specify FHIR Element Na[illegible]	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 sentenc[illegible]hole[illegible]distrib[illegible]r who is providing the parallel traded v[illegible]inary medic[illegible]oduct…" seems to refer to section 2.9 [illegible]ste[illegible]0).	Change applied.
Section 2.10; Line 672	9	User guidance and C[illegible]mance[illegible]ve different criteria as to when this [illegible] One is bas[illegible]n legal basis and one on the authori[illegible]on/r[illegible]tion/[illegible]tlement type. Expected they would [illegible]f[illegible]g t[illegible]e same data element.	Change applied.
Section 2.10; Line 673	9	FHIR path [illegible]rong[illegible]issing extension	Change applied.
Section 2.11; Line 674	6	Pleas[illegible]ify 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)~~. A reference member state is also assigned to veterinary medicinal products subject to~~ and an SPC harmonisation.	Change applied.
Section 2.11; Line 677	7	It is proposed to mention clearly that the VMPs subject to 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 reword as the word "decentralised MA" is mentioned twice and clearly defined that products are transferred in a MRP or 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	Name 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 transferred to MRP (following SPC harmonisation or referral) ~~and regulatory procedure applications (e.g. initial marketing authorisation applications, transfers, etc..),~~ that impact the product information as included in this guidance. The class is mandatory for veterinary medicinal products authorised in the EEA."	Change applied.
Section 2.13; Line 687	8	The term "product information" is used for the documents SPC/PL/LAB. But I think it means all info about the product, so also IB. This is confusing.	RMS list has been reviewed.
Section 2.13; Line 688	4	Table "CLASS OF PROCEDURE – DESCRIPTION" seems incomplete (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 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 is 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 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 ap
Section 2.13.1; Line 730	4	Table "TAG – DESCRIPTION", section "Value" It should be noted that the format for Centralised Procedure is different	ge applied.
Section 2.13.2; Line 733	5	This is a PMS extension – the Cross-Reference attribute in I P is not suitable for this since the cross-reference must re to another product. The FHIR path is not correct either s thi not related to the case. A new attribute at the MedicinalProduct level must be creat for this. How can the Conformance be Conditional? All ucts mu have this ID.	The c mance is mandatory as at the creation of the pr ct it does not exist yet. Modified to correct the description and the m ping.
Section 2.13.2; Line 733	9	If the identifier is to be generate UPD it is optional at product creation, it must not provided roduct creation; why 'Editable'?	Change applied.
Section 2.13.2; Line 733	9	ISO paths are related t ss re edicinal Product level, I understand t type of roduct identifier mentioned in this section is not a other UPD Product. Therefore the ISO pa not ar cable.	Change applied.
Section 2.13.2; Line 737	6	Please ve Element a ath	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 Gu is th D value generated by the system; or in t by th r? t statement says the system will ge In v case is conflicting to say that it's optional at time o ation. And is it correct that this is Editable?	Change applied.
Section 2.13.2; Line 737	9	Typo in tion 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 ~~(EU medicinal marketing authorisation approval routes)~~ through which the initial marketing authorisation in accordance with article 44, 47, 49, 52, 53 of the Regulation (EU) 2019/6 was granted ~~by the regulatory authority~~ must be specified.	Change applied.
Section 2.13.3; Line 764	7	Add to the examples provided: "Subsequent Recognition Procedure (2000000161	Change applied.
Section 3; Line 765	7	The title "pharmaceutical products is to be renamed "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 the section	Attribute has been removed.
Section 3; Lines 765-767	7	This section is not clear: we to s the routes of administration/target s es/with al period are organised and linked to th MP. And t should also be reflected in the co tual model	Change applied.
Section 3; Lines 765-768	6	When there are ore than on or administration, i.e. intramuscular sub s, at which level will the repetition take place (ro amin ation (768) or pharmaceutical produ 5), Route of inistration is NOT repeatable in the gu nce.	Change applied.
Section 3; Line 765	9	I th ource of AdministrableProductDefinition can e exp sed without: * adm eDoseForm (hard constraint, it is required as per 2020 t not as per Sep2020); * redient (soft constraint, legacy from the previous IG, can b anged)	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 766	5	Add text to further clarify why the section Pharmaceutic product is included in the vet IG although not really used for the vet products.	Change applied.
Section 3.1; Line 768	7	The words "of the pharmaceutical form" should be deleted as 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 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.	Change applied.
Section 3.2; Line 772	9	Conformance is mandatory however first sentence in User Guidance says " 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 behavour of deletions remains as agreed; this will have no impact on volume of sales reporting.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	C[illegible]m
Section 3.3; Line 775	3	The data element Withdrawal period is presented as optio[illegible] that the intention?	Change [illegible]d.
Section 3.3; Line 775	9	Withdrawal period class is optional and tissue, perio[illegible]nd note fields as well. Can we have a withdrawal period [illegible] tiss[illegible]e and no period or vice versa? Also only note and no [illegible]ue [illegible]period?	[illegible]nge applied: tissue and period are mandatory a[illegible]per FHIR standard.
Section 3.3; Line 780	7	The withdrawal period should be linked to the "a[illegible]strable product" and not to the "pharmaceutical product" cr[illegible]t 765 – 767. "Each withdrawal period will belong to ~~a~~[illegible]armace[illegible]~~cal~~ an administrable product on wh[illegible] route[illegible]d[illegible]istration and one or more species are [illegible]cribed	No change.
Section 3.3.1; Line 782	9	If a withdrawalPeriod cl[illegible] is include[illegible]issue is mandatory in FHIR R5 Preview 2	Change applied.
Section 3.3.1; Line 782	5	Please add son[illegible]ntifying As listed in T[illegible]ue (10[illegible]0072054) Only values with extended attributes o[illegible]eing "Edible and MRL Tissue", "MRL Tissue" or "Ed[illegible] Tissue[illegible]ould be used".	Change applied.
Section 3.3.2; Line 785	9	If[illegible]awalPerio[illegible]ss is included, value is mandatory in [illegible]R R[illegible]w 2	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 Example: "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 of the model has been added, which clarifies the relation with target species.
Section 3.3.3; Line 788	9	FHIR Element Name - should be corrected to last element in FHIR Path.	Change applied.
Section 4; Line 793	9	To remove the part 'And the same ingredient can be referenced in both the medicinal product 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 "Except when describing ingredients of manufactured items (section 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 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 the manufactured item and pharmaceutical product, when needed." But we no longer have ingredients referenced from pharmaceutical product.	Change applied.
Section 4.1; Line 801	7	Some manufactured items do not contain any active substance, in this case the ingredient role remains "active", an explanation shall be provided in the point 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 active substance, the excipient included in the product is flagged 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 it be possible to remove the restriction of providing always the term for 'Active'?	Change applied.
Section 4.2; Line 805	8	It may be entered optionally. Optional population is possible?	Confirmed.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outco
Section 4.3; Line 806	7	A table should be added to describe the Substance class: repeatable and mandatory.	he ingre cl s the substance class.
Section 4.3; Lines 806	3	It seems to us that the Substance class does not correspon to a natural grouping of data: The ingredient class has a r and a substance with manufacturer(s), strength and possi reference strength, but only the ingredient class i s repeatable grouping.	cted.
Section 4.3.1; Line 806	9	FHIR Element Name - should corrected to last element Path.	Change applied.
Section 4.3; Line 807	7	Why are the reference active substance an refer e strength not listed first as this i n is to all active substances whereas s /hydra sters not apply to all active substances (e.g. f enicol, pr uantel, tulathromycine, pimobendai s.). This will be in acc nce wit ate that states that the quantity in a ve mo is always required. In this case, th /ester will be optional depending on the act e subs ce pre t in the finished product. This will avoid tition of th ormation for the active substance no esent /ester).	Clarification provided.
Section 4.3; Line 807	5	We s not u harmaceutical product	Change applied.
Section 4.3; Lines 810-811	3	ubsta class cannot be repeated. If multiple active ing ents are to be specified, the Ingredient class needs to be rep ed.	The class is repeatable.
Section 4.3.1; Line 813	6	P e verify FHIR Element and Path	Value of the FHIR path reviewed and FHIR name removed as it was redundant with the FHIR path.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcom
Section 4.3.1; Line 813	5	Propose to clarify what should be given as "active" substance where not obvious. NOTE: Every medicinal product must have at least one acti substance. For products that are not regarded as having real active substance, the "main substance" of the produc ould be given (e.g. sterile water, sodium chloride). For ho pathi products, the final dilution/trituration(s) added to t uct should be stated. Change ISO Path to: /MedicinalProduct/PackagedMedicinalProd PackageIte m/Man ufacturedItem/Ingredient/Substance	ange ed.
Section 4.3.2; Line 814	9	FHIR data type for all strengt ce st h values is "decimal". This only accepts ull stop e decimal place. The examples have a comma. http://hl7.org/fhir/2 May/ ypes #decimal	Change applied.
Section 4.3.2; Line 814	5	A clarifying secti with exampl ding active substances of homeopathic eri icinal products is required, including accept ge o fferent expressions for degree of dilution It w be to ta the human EU IG where a decision tre ei au that illustrates the different cases. That tree shoul nclud also here and the text altered to go with the A ern ta e for different types of products has also been incl d in the human IG and should be considered here.	Please refer to Chapter 6 (Examples).

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outco
Section 4.3.2; Lines 820-825	3	On "The expression of strength": The first sentence claims that "The expression of strength for 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.	larifie the t conformance cannot be changed, 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 (i.e. base, acid or anhydrous material)". However, in the examples given, the strength is expressed in terms of the hydrate or salt.	Change applied.
Section 4.3.2; Line 838	7	Examples shall also provide for immunological products.	Please refer to Chapter 6 (Examples).
Section 4.3.2; Line 849	7	It is not "and/or" it is because strength is provided by presentation or concentration, not both.	Change applied.
Section 4.3.2; Line 849	5	And/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 term is incorrect. The concentration strength is always per 1 unit of the denominator. If it is expressed as per 0.8 ml, then it 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 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 ~~Pharmaceutical Product~~ 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 "type 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 be 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, which strength expression to be used.	Rejected.
Section 4.3.3; Line 879	9	Remove reference to pharmaceutical product	Change applied.
Section 4.3.3; Line 881	9	The only active substances can be added, is this sentence now required? Potentially makes reader think they can add any ingredient in any role.	Change applied.
Section 4.3.3; Line 882	3	Please leave out the editorial comment in italics.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 4.3.3; Line 882	5	We do not understand the EXAMPLE: If maintained, use oxy... HCl / oxytet example above Oxytetracycline HCl / oxytetracycline (concentration strength). Also, could the value "1g" as Active and Referenc... tab... be explained, i.e. where it would come from for this p...	...hange appl...
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 ...like Substance in point 4.3.1 before the reference strength ...nt 4... (line 874)	Change applied.
Section 4.3.3; Line 887	5	Change in ISO Path /MedicinalProduct/Package...edicinalPr...ct/PackageItem/ManufacturedItem/Ingr...nt/S...nce/S...ngth/ ReferenceStren... ReferenceS...	Change applied.
Section 4.3.3; Lines 889-891	3	Please reuse th... word... ...e lines 863-866, suitably adjusted.	Change applied.
Section 4.3.3; Line 891	6	Please... FHIR Eleme... ...nd 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	Fi... at... ont... 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	Correction proposed The denominator shall be expressed with a unit of numeric value and a unit of presentation (e.g. tablet) or a unit of measurement. The units for the denominator must be specified as [illegible] and a Term ID as listed in Units of Presentation (2000000[illegible]4) or Units of Measurement. /MedicinalProduct/PackagedMedicinalPro[illegible]/PackageItem/Manufactured Item/Ingredient/Substance/Strength/Referen[illegible]Strength/Strength	Change applie[illegible]
Section 4.3.3; Lines 895-897	3	Please reuse the wording of [illegible]lines 8[illegible]70, suitably adjusted.	Change applied.
Section 4.3.3; Line 897	6	Please verify FHIR Ele[illegible]ent a[illegible]ath	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	/MedicinalProdu[illegible]Packa[illegible]dicinalProduct/PackageItem/ManufacturedItem/I[illegible]/Su[illegible]ance/Strength/ReferenceStrength/Streng[illegible]	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 5; Line 898	5	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. 2) Heading: Please, Add (ID Level 2) 3) Clarify text in user guidance: As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Ide[illegible]ar (or Permanent ID) is a unique identifier o[illegible] veterinary medicinal product in the Union product data[illegible] This Permanent Identifier ~~ensures that~~ diff[illegible]entiate [illegible]we[illegible] the veterinary medicinal products a[illegible]sev[illegible]mber States from the same MRP/DC[illegible]or ~~RUP~~ S[illegible]~~re identified based on a set of~~ It is genera[illegible]based on [illegible] Product ID (Level 1) with the addition o[illegible]natic[illegible]nform[illegible]on as authorised in the country by the [illegible]evant compe[illegible]uthority and representing the [illegible]call[illegible]al entitlement'. Note: The Permanent Identifi[illegible] elen[illegible]t will be given by the time of initial cr[illegible]or products [illegible]n CP, NP and Registration proce[illegible]es b[illegible]~~tion~~[illegible]t blank at the initial creation of the vete[illegible]icin[illegible]roduct within MRP/DCP into UPD.	Change ap[illegible]
Section 5; Line 898	9	FHIR pa[illegible]to th[illegible]echnical ID of the FHIR resource. Should [illegible] a bu[illegible]identifier? FHIR path would then be .identifier with [illegible]ystem/value of "updId" or similar.	Change applied.
Section 5; Line 902	3	The d[illegible]nction between the Product identifier and the Perm[illegible]ent 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 a 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 and 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 reference to the packages in order to submit volume 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 "in English, or in both." means. If package description repeatable, how to deal in DC|MR procedures with the EN description provided by the RMS and the national lines provided by CMS?	Change applied.
Section 6; Line 905	9	It has been proposed 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	Outcom
Section 6; Line 913	2	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, applicable PCIDs as authorised in the relevant national territory among the available PCIDs as provided by the [illegible]. This meaning that there will be no unique ID for a package in a specific MS. 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 driven down to the country and is dependent on 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 [illegible] better suited, as it allows direct mapping of packages marketed in a specific country to sales quantity.	Acc[illegible] the Vet EU IG, in order to submit the volume sales for 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.
Section 6; Line 913	3	Given that "PCID is a well defined term from IDMP and given that UPD does not contain the MPID that constitutes a part of the PCID, please avoid referring to any human-readable UPD product ID as PCID".	Reference to PCID removed.
Section 6; Line 916	5	Proposed clarification 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.	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 pl… specify on which level the repetition shall occur (6, or 6.1…	A 'class … kage medicinal product has been added to p…vide more clarity.
Section 6.1; Line 929	7	A Packaged product class shall be added before 6.1 wi… "yes" at repeatable in order to have several package des…tion/pack sizes for a veterinary medicinal product. The packaged product class shall include : - 6.1 package description, 6.1.1 Language, 6.1.2 C…y - 6.2 Pack size - 6.3 Package identifier - 6.4 Legal status of supply - 6.5 Marketing authorisati… leve…1 Marketing authorisation number (pa…ge leve… 5.2 C…untry	…class' for package medicinal product has been a…d to provide more clarity.
Section 6.1; Line 929	2	6.1 Table: products auth…ed via CP… ckage description 'added by whom?'… miss… only m…tioned for MRP/DCP/NP.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 6.1; Line 929	5	Proposed change (if any): Proposed clarification 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. For MRP/DCP, the English version from the eAF can be [illegible] the RMS to populate by the end of procedure. In many cases will need to be edited (separated) so that each package description only describes one package. Products authorised through NP The package description is to be [illegible] the local language(s) of authorisation in line with the national SPC. Products authorised through the centralised procedure The package description to be provided in English and local language optional in line with the national translations of the SPC.	Change applied
Section 6.1; Line 929	3	The first bullet of the guidance concerning MRP/DCP/RUP products seems to be incomplete or to contain text that should have been deleted. We support that package description in English is required and that the RMS may add package description in the official language(s) of country. The description concerning CAPs does not state, who is to provide the description – please specify.	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?	Alth[illegible] the [illegible]R standard only allows one [illegible]escr[illegible]eld to [illegible]e associated with a package, [illegible]he fact [illegible]thi[illegible]ement is a free text field will [illegible]llow the u[illegible] introduce more than one [illegible]nslation when applicable (e.g. Belgium could p[illegible]e the description of the package in its three offic[illegible]anguages in the same field).
Section 6.1; Line 931	5	On all examples, add text in red as proposed bel[illegible] 1) If text is in the SPC Section 6.5 Nature and comp[illegible]n of immediate packaging is: Xxx The Information to be entered in UPD [illegible]ge description [illegible] first package should be: Xxx Information about how to hand[illegible]listers [illegible]h[illegible]D are missing in the first example[illegible]elete [illegible]SPC t[illegible]or add description for the UPD. The examples in Spanish a[illegible]rench sh[illegible]d be changed into English and inform[illegible]n for U[illegible]e added or the example be del[illegible]d. Or it should be clear that we have examples in th[illegible]ges (which is probably not very valuable in this [illegible] Add [illegible]ple on com[illegible]tion packs, e.g. 4) [illegible]ext i[illegible] SPC Section 6.5 Nature and composition of imm[illegible] pack[illegible]g is: Boxes [illegible]& 1[illegible]als of lyophilisate and 1 & 10 vials of [illegible]ensi[illegible] T[illegible]nformation to be entered in UPD Package description of firs[illegible]ackage is: Pl[illegible]c box of 1 dose + 1 ml vial [illegible]astic box of 10 x 1 dose + 10 x 1 ml vial	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outc
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	C pplied.
Section 6.1.1; Line 943	5	The given ISO Path will not work since this attri e in the ISO path is not coupled to the package. You nee ext on just as you do for the language.	in this section
Section 6.1.2; Line 946	6	In the user guidance box the word 'name' seems t g here.	Change applied.
Section 6.1.2; Line 946	9	I don't understand this. Why is coun luded h e as this is specified in section 1.7.3.1 is no nk a PackagedProductDefiniti esou one ticular MedicinalProductDefini .name	Change applied.
Section 6.2; Line 949	3	The description only sp of units presentation but the example with bottle turally uses ml (unit of measureme as the basis for the pack size.	Change applied.
Section 6.2; Line 949	9	Marketing atus should be provided at package level when th thoris on is granted at this level, otherwise th introduced product level will apply to all packages e.g. s d). Also, we could align with the human domain point	Change applied.
Section 6.2; Line 950	5	Ad t f arification: The p ize describes the number of units of presentation of a anufactured item in a packaged medicinal product, i.e. the meric 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 ~~250~~ (numeric value) bottle (unit of presentation), the quantity 250 ml is described in the (Manufactured idem quantity described i manufactured item section)."	Ch applied
Section 6.2; Line 959	7	A packaged medicinal product has only one pack s . The "Packaged medicinal product class" is repeatab ut th ack sizes field not. "Repeatable- No ~~Yes~~"	nge applied.
Section 6.2; Line 959	7	Add an example of a pack size of a p duct with a v wder and a vial of solvent: "The pack size of a product with 1 vial wder 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. how is relate to section 6.6.1?	Change applied.
Section 6.2; Line 961	7	Example(s): 10 (tablets), (tablets), 2 (vial of solvent) + 1 (vial of powder)	Change applied.
Section 6.2; Line 961	5	What if thei era anufactured items in one package? Plea d examples fo package containing e.g. two vials, wi a powde one with a solution.	Change applied.
Section 6.3; Line 962	9	t s tates that this is assigned by UPD. i.e. the s gene es this value. Therefore, not correct to also say is op create?	Clarification provided.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcom
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 identifi related with the IDMP PCID?	Y kage ID is stable. As p use ne package identifier, make sure th lue must not be supplied for CREATE b must be supplied for UPDATE. e package identifier will be generated by the m and must be seen as an opaque structure.
Section 6.3; Line 962	5	"The PCID data element is optional at the initia eatio the veterinary medicinal product into UPD." Is should be further described what "optional" mea e. I different for MRP/DCP (blank?) and C NP. And/or ot reasons. Also, PCID or other ID to be defined (as sse rlier in the document).	Change applied.
Section 6.4; Line 963	7	Add package level to the ading 6.4 Legal status of the s ly (packa evel)	Change applied.
Section 6.4; Line 963	5	Add text in headi or cl tion Legal status o pply (packa)	Change applied.
Section 6.4; Line 963	3	There is ong q di in the SPOR Vet expert group about how to handl ses ere different pack sizes have diff gal status of pply. P se r the t to reflect the outcome of this discussion, ev .	Noted.
Section 6.4; Line 972	3	Th Path ven for Legal status of supply at package level seem ncorrect (would seem to apply to the product el).	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	e 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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" repeatable. "Repeatable- No ~~Yes~~"	Change applied.
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 (e.g. connected to the IRIS platform) the sales data remaining in scope of the UPD and a document is required that provides transparency on data field requirements. Proposed change: Reintroduction 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 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	"Manufactured item class" is mandatory, why the "unit of presentation" is Conditional? The details 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 'lyophiliase for emulsion for injection'. If it is possible then could be cases where several Manufactured Items could be exacly the same.	Change applied.
Section 6.6.3; Line 1024	5	Medicinal Product ABC 20mg/ml powder and solvent for solution for injection (combined pharmaceutical form) presented as 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 Review 2	Change applied.
Section 6.6.3; Line 1032	3	The Manufactured dose form seems 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 the "solvent for solution for injection" is considered a manufactured dose form. The quantity of ingredients in the case of solvent is not always clearly defined. Citric acid 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 product (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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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, repeatability, 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 missing	Change applied.
Annex; Line 1042	5	I think there is an Annex missing (Annex 2) where it is specified 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 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 for registered homeopathics, parallel trade products.	Fields will apply to all products unless specified otherwise in the condition.
Annex 1; Line 1042	9	If any changes/additions/performance, the corresponding entry in this Annex should be updated	Change applied.
Annex 1; Line 1042	9	Ref. 2.13.1 mandatory	Change applied.
Annex 1; Line 1042	9	Pharmaceutical Component in brackets about MP or pack level is not applicable	Change applied.
Annex 1; Line 1042	9	Ref. 2.13.1 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.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 ap
Annex 1; Line 1042	9	Ref. 4.3.3 the attribute and not the class is mandatory	Cha applied.
Annex 1; Line 1042	9	Ref. 6.6 review section references - some are not correct 5.6.2 (wrong number) is duplicate to line above	Change a ied.
Annex 1; Line 1042	9	UPD IA Annex, i.e. IA Ref, 3.1 should be 3.10 for Withdra period tissue, period and note	C ge applied.
Annex 1; Line 1042	3	It is not clear to us how much data needs to ubmitted by the RMS for products approved according to M CP/RUP for the individual "national" products in t erent We think that it is important to a as s s pos e on the processes surrounding the UPD. The current description is to a la extent ba d on the data that needs to be found UPD ful submission and important details the pr esses seem to be still missing. The process for subm hed documents" is one additional example: s the d ment be submitted in advance in o get the UP dentifier? – if so, why does the FHIR st ure h doc ment content as mandatory?	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.
Chapter 3			
	2	Th chapte s no rovide any clarity or guidance on how MA t pro 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 prod and information on changes to existing veterinary medic products following completion of a variation procedu another regulatory procedure, as applicable."	Ch e ar d.
Section 2; Line 27	7	The upload of legacy data is not covered in this nte proposal to add upload of legacy data : "NCAs should electronically submit into the UPD infor n existing veterinary medicinal produc the date of ap ation of the VMP-Reg, newly authorised vete medic products, information on cha existi ary medicinal products follow comp of a ation procedure or another regulatory pr dure, as a cable"	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 ly forese that marketing authorisation h s may nation to the UPD through the inter Marketing au ers with many approved products will presumab nt to 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	ther c endpoints for each type of product or type of p e? If ye eas etail.	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	e sol s mentioned are not described in Chapter 1.	Chapter 1 is an introduction, detailed description given in Chapter 3.
Section 2.1; Line 59	3	T wording "notify changes" sounds slightly inappropriate if the ect is an amendment of the existing information – just as in the previous bullet. Who submits and who is notified?	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 a data request with the product status NULLIFIED in its corresponding RMS term for
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.
Lines 81-171	1	Regarding variations, it is unclear in which cases the MAH should submit the changed data to UPD and in which cases the NCA should submit the changed data to UPD. I suppose it should be submitted from both.	This is specified in the implementing act and in the last 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 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 to legacy products once they have been uploaded to 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 renewed products authorised before 28 January 2022)" Comment: I assume that products authorised before 28/01 which have not yet been renewed must go through a renewal process. This is still under discussion and a Commission response is necessary needed.	Change applied.
Section 3.2; Line 130-132	2	The sample 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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?	Thi[illegible]ould [illegible]considered best practice, there are [illegible]o le[illegible]dlines [illegible]t this point in time.
Section 3.2; Line 130-144	1	Does this imply a requirement that the NCA is capable to [illegible]iver the information in FHIR format for all variations? Fro[illegible]hich date?	[illegible]legacy data, only submission of the latest [illegible]n of product as authorised. Any subsequent cha[illegible]ges 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 [illegible]the MAH who can nullify the product in the UPD.	Change applied.
Section 4; Line 161-162	2	By the phrase 'once the regulatory pr[illegible]re is complete[illegible], the 'Process' appears to be written only for c[illegible]of pla[illegible]on market, availability status & s[illegible]n / re[illegible]. However, it does not correctly descri[illegible]he pr[illegible]for V[illegible]A. As written, it implies that for VNRA 1[illegible]AH submi[illegible]package, 2) CA approves 3) MAH updates[illegible] This is[illegible]t what is proposed and imposes an[illegible]d burde[illegible]	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[illegible]racket[illegible]"EP311 Update Product"	Change applied.
Section 4; Line 172-173	2	MAH urgently[illegible]how and when details on the format f[illegible]submission will[illegible]available.	Noted.
Chapter 4			
Scope; Line 26	11	[illegible]iona[illegible]tion on Page 3 regarding the status of pr[illegible]may [illegible]needed – exact date on which legacy MAs/[illegible]s should be valid. [illegible]posed[illegible]t: "For the purpose of this chapter, legacy data is d[illegible]ed as any data on a veterinary medicinal product a[illegible]orised in a Member State with a marketing authorisation or [illegible]istration valid on before 28 January 2022."	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Scope; Line 26	2	From the MAH perspective, the IG does not provide any detail on the legacy data upload timeline or organisation. More information and clarity on these aspects is desirable to assure MAH that the upload will be completed in time for a meaningful period of MAH access, mapping and testing before going live.	Comment noted.
Scope; Line 38	5	authorised or registered in a Member State by 28 January 2022	Change applied.
Scope; Lines 43-44	8	What is the UPD product id? The permanent identifier should be sufficient to identify 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 ~~temporary~~ file upload (single or batch).	Change applied.
Section 1; Line 59	5	~~As a temporary~~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 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	Should the XML file or any part of it (i.ee.g. terminology) be recognised as not being compatible with 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 batch 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	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.' Comment: The submission planning roadmap in the Introduction chapter line 127-128 shows that the 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 the 1st upload, as the UPD IDs of products created by the RMS are not known to CMS prior to creation of the record. The Agency must support at least 2 XML uploads.	Change applied.
Section 1; Line 66	5	NOTE 2: ~~The Agency has the capacity to upload XML File(s) only once for each NCA. Therefore, this~~ 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 should 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.	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 map	Change applied.
Section 2.8; Line 195-197	3	The update in question does not affect substance ID b other attributes of the substance in the E list.	Change applied.
Section 2.8; Line 199	2	NOTE: At present, veterinary s are ng cleansing in SMS. This is ex ted to mple d by end January 2021 at the latest Comment: Vet Substance C sing is s not completed (VMP-Reg Stakeholder ting 25	Change applied. The Vet Substance cleansing has been completed.
Section 2.8; Line 202	5	Concerning this xt: "F terinary vaccines and proteins substances, th not currently include translati : if the substan name in English is provided for the rele tance, th CT ID shall be used to provide the v nary information in UPD. Meanwhile, a change req upda he existing substance ID shall be provided ia the Service Desk portal to submit the missing slatio It ot clear form the text what is expected by NCAs co ning 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	6	Table ends with 6.5.1, is this intentional?	Comment applied.
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 these requested documents in the proposed format will make the upload too heavy.	Comment not accepted.
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 MAH's must 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 parallel 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.	Comment noted.
Section 3; Line 226	10	2.5. Authorisation status; is for the upload of legacy data, only the "1" for valid will need to be provided, we suppose.	Confirmed.
Section 3; Line 226	10	3.1. 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 element type "Marketing authorisation": "Performance in chapter 2- ~~Mandatory~~ 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 legacy data" SPC is not available in EN in national database but available CTS.	Comment noted.
Section 3; Line 226	7	(authorised dose form) is mandatory in the chapter 2: "Conformance in chapter 2- Mandatory ~~Conditional~~ (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 product level not the package level: "Conditional ~~(either at MP level or at PP level)~~"	Change applied.
Section 3; Line 226	7	The name of product in English 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 QQP is available in the national database. This information should be provided by MAH: "1.9 Contact (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	Package as structured data is not available in national database and will not be uploaded for legacy products: "Package 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	Outcom
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 w need to provide them separately?	Onl uld be sufficient for legacy data.
Section 3; Line 226	10	In the latest implementation guide, it is also foresee at the ingredient needs to be uploaded. In the RMS list 4.1. 'ingredient role' , not only " ien s mentioned, but also "solvent". How is solvent to b erstoo Do we need to provide the excipient as part of the p t also the excipient that is part of the f cation process not per definition in the end product? If the ent need to be provided too, in practice that w mean th put of an expert is required which is addi burd or NCA's and for experts who are alrea overload ith work. In the initial upload it should be clear y the act substance needs to be uploaded. When cipie d s nts are to be provided at the submis of an initial a ation this is considered to be extremely he g and practically impossible.	nge applied.
Section 3; Line 226	10	4.3.2. Strengt itati composition; 4.3.3. Reference stre he number ements in these two sections that we to has harged significantly. It is very hard for us t w to erstand these different elements. We are quite sure have the information in our national database, owev re unable to link the fields in our national base 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	C the information regarding the package description be sent 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 are mandatory 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 distinct data elements, 2.4 and 2.9. The FHIR path 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	Cells 6.1 to 6.4 equal. The FHIR path given does not appear to be correct.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Section 3; Line 226	3	Class 1.10 Attached Document: detailed data fields and the references to FHIR data elements suggest a process where t document itself (the contents of the document) is submit part of the overall data submission. This is not in line with the previously described pr s of first uploading the document in order to obtain a UR D for nd then submitting the structured product data co a reference to the document by means of the obtain PD I	Cha pplied
Section 3; Line 226	10	It is not clear to us how we need to derstand the u of the Veterinary medicinal product nar • 1.7.2. As we understand it, there will st or x ID applicable to all : Full Nam 0000 • 1.7.3.Country / Langu s should inked to the full name of the product. Since there are th nat l langu s, this would mean for Belgium: free text ful me / 0000001 / BE – FR free text ful 220 000001 / BE – NL free full name / 22 0000001 / BE – DE H eve n our n DB, we do not make the distinction in re ges, when it comes to the VMP product name. F does have the active substance name in German.	Change applied.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outco
Section 3; Line 226	5	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). 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.	ome are marked as conditional.
Section 3; Line 226	5	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).	Change applied.
Section 3; Line 226	5	Proposed change (if any): For clarity, please add Mandatory in front of all comments in N column i.e. Mandatory For allel traded only, Mandatory on or h ase sites Mandatory at en a free text	Change applied.
Section 3; Line 226	5	It sh clarified whi ocument types that are mandatory fo ch t legac roducts (preferable in a separate table 2 e d fo ating mandatory data per product type).	This is information is provided in Chapter 2.
Section 3; Line 226	8	For dat pload the dataset needs to be enriched with MS co st. mapping purposes business identifiers will be needed as di ssed in the legacy data upload subgroup. Shall we mention th n 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	y 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, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
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 3; Line 226	9	Ref. 3.3: If include withdrawal period, has to be 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 extra field in UPD: Classification if the product is classified as a Controlled Drugs. – YES/NO This is a national option 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	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 on the information available last year on this topic, the current scope - and consequently the impact on workload and technical development- has increased substantially. We observed: 1/ a substantial increase of data fields, for which there are several we are unable to deliver. 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 [illegible] 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 3.6 "Attachment"). It is not just a matter of foreseeing a 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. Conclusion: For Belgium the increase of scope regarding the upload of legacy data make it impossible to deliver the required data within the same timeframe. FAMHP is however able to perform a load based on the first 21 data fields set-up initially.	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	Ou e
Annex I; Line 227	2	Important guidance document missing; OMS Guidance on Assessing Organisation Names and Location Data.	Change ap
Chapter 5			
Section 1; Line 15ff	2	The vet EU IG Chap 5 appears to be a copy-paste f the human PMS EU IG chapter 6 (apart from a UPD/ swi). It is important to remember that IDMP is not a leg requirement for the veterinary sector and only the parts/elements of SPOR that are comm to both domai the veterinary-specific data elements) a ided by t e veterinary Business stakeholders ould be lied the UPD and related systems.	The t was amended to isolate it from ISO and focus more on UPD.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outc
Section 3; Line 42ff	10	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 would 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 provide information on: 1/ How the files will be exchanged. This is according to us insufficiently detailed. We request to provide more concrete details on data-exchange in chapter 5: Technical specifications. 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 (change) or a separate profile for the initial upload is foreseen. This needs to be clarified. 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/).	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.
Section 3; Line 42ff	10	Concrete example of all the required fields (as wel as a pdf in base64), in the expected format/xml. 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).	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.

Section, Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcom
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 X files)	The ... arity is ... 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 PD... ocuments that need to be included in the legacy data uplo...e	...ment noted - this is out of scope of the gu...nce provided in this document.
Section 3; Line 42ff	10	Milestones: We would also like more information o... requested deliverables and milestones or timing linke... This would enable FAMHP to anticipat...ilability of the ... department. Important for FAMHP is to ...n for e...ple when exactly we need to sta... whe... start analysing more in detail th... HIR p... and X...L or JSON scheme and when we can ...pect furth... echnical details on the API, UI and file upload int...ces that ... be available.	NCAs are invited to join the informal UAT group where more detailed, regular updates are provided.
Section 4; Line 55	2	The following se...nce does ... account of differences between the v...erinar... human sectors and is written for PMS for huma... ...he resources as defined in the current API specification ... coverage for the full IDMP model. The ... implement...n of the ISO IDMP format and ...cture... done in phases. Therefore, relevant data el... and ...ources within the overall FHIR model will be enfo... with ... 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	...it pos... to provide a FHIR profile describing the structure ... content of a whole veterinary medicinal product as r...ested for UPD? This complete profile could be used by NCAs ... 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.