25 January 2021
EMA/633341/2020
Management Board

# Overview of comments received on Union Product Database (UPD) Access Policy (EMA/198149/2020)

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

| Stakeholder no. | Name of organisation or individual |
|---|---|
| 1 | Agencia Española de Medicamentos y Productos Sanitarios |
| 2 | AnimalhealthEurope |
| 3 | Association of Veterinary Consultants |
| 4 | Bundesverband der Pharmazeutischen Industrie e.V. |
| 5 | European Commission – DG GROW IT |
| 6 | Dogs Trust |
| 7 | European Group for Generic Veterinary Products |
| 8 | Federation of Veterinarians of Europe |
| 9 | Société Nationale des Groupements Techniques Vétérinaires |

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# 1. General comments – overview

| Stakeholder no. | General comment (if any) | Outcome (if applicable) |
|---|---|---|
| 3 | I have only one comment, this seems a high administrative burden for small and medium enterprises, not only to enter all relevant information also to keep up to date with the technologies to fulfil all legal requirements. | The initial entry of product data in the UPD is the responsibility of the competent authorities. The maintenance of product data in the UPD will be shared between the competent authorities and the marketing authorisation holders, and the competent authorities are responsible for providing the majority of the data (e. g. updates arising from the conclusion of post-authorisation procedures). The administrative burden will consequently affect mainly the competent authorities.<br>Furthermore, in order to support the users in fulfilling their obligations, the UPD will provide a portal through which all operations required for the marketing authorisation holders can be carried out. Therefore, the updating of local technologies will not be essential to comply with the requirements arising from Regulation (EU) 2019/6. |
| 3 | And in case of third party providers how will the UPD Access work? | Third party providers will always perform their UPD duties on behalf of a marketing authorisation holder. A 'super user' of the relevant Marketing Authorisation Holder will be responsible for approving the role request that will give access to the third party providers to the UPD, i.e. access is controlled by the Marketing Authorisation Holder that is the product owner for a specific entry. |
| 3 | If the UPD is working as described it would be okay however without to test it on a dummy version (test environment) it is hard to evaluate the access policy. | The Access Policy must be in place to develop a system that can be tested. Different UPD components and their relevant accesses are being tested during the development by representatives of the different impacted user groups. Should the need arise to amend the Access Policy at a later stage, this will be possible also before the routine review 3 years after adoption. |

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| 5 | There is no reference to a formal risk-based approach to access control. Of course there is the application of Need To Know principle (3 different user profiles) and reference to GDPR as well as mention of sensitive data of commercial nature. But the latter would require a more formal Business Impact Assessment (BIA) in order to know exactly the impact in case of loss and therefore the level of protection needed. The BIA approach is mature in the EC IT Security Policy (ITSRM2 methodology) and is highly recommended. | EMA is indeed looking into using the ITSRM2 methodology but has no concrete timeline for this yet. |
| 5 | In table 2, rows 3,4 and 7,8 are identical although it is evident that rows 7,8 are referring to a more limited scope (i.e. marketing authorization holders dealing with own data). How this limited scope will be reflected for example when the authorization holder will use the API? | MAH access to the API is controlled via Authentication and Authorisation. Users (or systems) can only access the API after they have been authenticated through a log-on process, the authentication step. After a successful log-in / authentication, what a user can do (read /write) using the API will be determined by role-based access control (RBAC), the Authorisation step. Authorisation will be further divided into what actions can carried out on the data and what data a user can access. This is 'row level' security and determines which veterinary medicinal product a user can access based on the affiliation to an organisation. |
| 5 | There is no back-office mentioned although it is implied (for example by the fact that in Annex A no data is actually ever deleted by any of the mentioned profiles). Will there be a super-user for administrative tasks and notably access to logs (crucial in case of sensitive data)? Logs and Access Control Lists, although supporting assets are having an important role in security which needs to be evident in the document. | All EMA production systems have access control mechanisms in place which limit what logs can be retrieved and which system actions can be carried out to admin/super users with elevated privileges. |

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| 5 | Will there be a process for registering, authorizing and removing access control rights as line 218 implies ("UPD registration process described in the registration guide")? If yes, shouldn't it be part of the document (annex)? | The registration guide will be developed and published in due time before the launch of the UPD. For reference, the registration and authentication will be performed through an integration with the existing Identity and Access Management (IAM) tool, and thus the same approach and rules will apply there. The specificities, such as precise role descriptions and their level of access for the UPD will be incorporated to the registration guide. |
| 5 | It is not clear if data would be replicated to MS authorities systems (the use of APIs might imply this). In that case the security perimeter is greatly enlarged making security controls (at the MSs) impossible. It would be useful to know if sensitive data would be replicated to MS systems. | The access to the API and its use will be subjected to prior acceptance by the user of the EMA - API General Terms of Service - Terms of Use, a document which is referenced in the final Access Policy. According to this document, it is the responsibility of the user of the API to guarantee the protection of the data retrieved:<br>"3.2. Conditions of Use<br>(c) You will ensure that any non-public data, classified as confidential or restricted, retrieved via the API with elevated access privileges, will not be accessible to Third Party Service Consumers who have not been granted appropriate access privileges. The data classification mechanism will be specified as metadata, i.e. data classification information provided in additional attributes, or in the API documentation." |

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| 8 | FVE understands the reasoning of categorising veterinarians in 'general public', as no specific login function will be foreseen for them. Nevertheless, we regret that the Access Policy does not refer in more detail to veterinarians as they will be a primary user of the database, while the 'general public' will probably not often use the database. Most veterinary medicinal products require a veterinary prescription, so it would not be beneficial if farmers or pet owners would go 'shopping' using the information retrieved from the UPD for veterinary medicines online. Therefore, we suggest to change the term 'General Public' into 'Veterinary professionals and other interested persons' | Comment applied.<br>The term 'General Public' is used in both the Commission Implementing Regulation (EU) 2021/16 and the Regulation (EU) 2019/6 to refer to all persons or collectives that do not belong to the group of competent authorities, the Agency, the European Commission or Marketing Authorisation Holders. However, a clarification has been added to the section in the Access Policy where the Stakeholder groups are defined (4.2.1). |
| 8 | Vital for its usability is that the system will be user-friendly with an easy and practical search function. The "Product Database" should be easily readable, and written in a clear and concise way, and containing precise, accurate and useful information to take a decision on veterinary therapeutic activities. In case of suspension, revocation or drug shortage problems, mechanisms should exist to update the database in a timely manner and to alert the veterinarians checking the database. | The UPD will provide simple and efficient access to information and is conducting user research to facilitate this. In relation to the functionality for communicating through alerts the occurrence of certain types of changes, its implementation will not be included in the first release. Nevertheless, the importance of such alerts is understood and belongs to the set of functionalities that will be considered for prioritisation in the immediately subsequent phase(s). |

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| 8 | Veterinarians, no different than the normal public, are using mobile devices more than fixed desktops. This is the case especially for large animal veterinarians visiting farms. Therefore, mobile-friendly access to the UPD would be hugely beneficial, will increase the use of the database and give trust in being technological advanced. As an important point is that the UPD will be functioning when the new veterinary regulation will be applied in January 2022 we would understand that a two phased approach is chosen and priority would first be given to a desktop version and a mobile version then to follow afterwards. | As stated in the Art.6.3 of Commission Implementing Regulation (EU) 2021/16, the graphical user interface of the Union product database shall support responsive web design. Consequently, it is foreseen that the UPD Public Portal will comply with this requirement. |
| 8 | One important question has to do with the language of provided information for SPCs available only in certain EU languages. Will the core components be translated in English? | The SPC documents will be published in the language of the Member State where the product is authorised, apart from centrally authorised products where these documents are translated into all the official EU languages. Many fields in the UPD utilise controlled vocabularies, i.e. controlled lists of terms, for which translations will be available. Free text fields will not be translated. |
| 8 | Ideally the UPD should be linked to the Pharmacovigilance database, so that when searching up a specific veterinary medicinal product, the veterinarian can also have a look immediately at the adverse events recorded. | The access policy is applicable for the UPD and its associated fields only. Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16, do not require the inclusion of adverse events information in the UPD. However, it is noted that the functionality specified would be very useful for veterinary healthcare professionals, therefore a potential cross-reference to the adverse event portal (adrreports.eu) will be considered in the user research activities for the UPD portal. |

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| 9 | For the moment 3 access levels are planned: administration (medicine agency, the competent national authorities and the European Commission), marketing-authorization holders and the "general public".<br>There is no specific access planned for prescribers such as veterinarians; however, it seems to us that veterinarians should have a higher level of information than the “general public”, in particular in terms of pharmacodynamics and pharmacokinetics, the Summary of Product Characteristics data being sometimes more than succinct. It would also be useful to have information on the trials which led to the marketing authorisation.<br>We ask that practicing veterinarians should be able to have access to more complete data than those provided today in the "general public" section.<br>We are proposing that the final marketing authorisation report will be posted online, including comments from member states and the laboratory's responses, at least for parts III and IV of the MA dossier.<br>For clinical trials, we want certain data to be accessible, including in particular the number of animals included, the inclusion and exclusion criteria, the product with which the tested product was compared, the criteria and rate of cure. | The complete description of the information that will be made available through the Union Product Database is specifically defined in both Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16.<br>Additional information on the pharmacodynamics and pharmacokinecs will be available in the public assessment reports published as part of the documents associated with the relevant product entry. Veterinary healthcare professionals, as part of the user group "general public", will have access to all the information that exists in the UPD except the data considered commercially confidential or personal data (see Annex in the Access Policy). |

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| 2 | AnimalhealthEurope is grateful for the opportunity to provide comments to this draft policy, and would like to raise the following points:<br>Our overarching and critical concern is that a primary objective of the review of the legislation was to reduce administrative burden for all parties, and this is in real danger of being lost.<br>We urgently request that this objective is once more placed centre stage in relation to the operation of the UPD and all its ancillary features (even if these are not specifically included in the legislation, for example the new eAF). The current size of the regulatory burden disproportionately impacts the veterinary medicines sector, and this was a key conclusion arising from the original impact assessment preceding the drafting of the Regulation.<br>The UPD access policy does not seem to take into account all the expected functionalities.<br>AnimalhealthEurope would like to remind the importance of developing tools that are fit for the purpose and that contribute to reduce the administrative burden footprint.<br>There is a need for a swift and non-burdensome process in case Marketing Authorisation Holders (MAH) need to request correction to certain UPD data sets. | According to Commission Implementing Regulation (EU) 2021/16, the holders of a marketing authorisation are responsible to notify the relevant competent authorities or the Commission, of any data quality issues identified in their products that are registered in the Union Product Database. In turn, the competent authorities or the Commission are responsible for correcting the data upon verification that the requests are justified. |

| Stakeholder no. | General comment (if any) | Outcome (if applicable) |
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| 2 | Roles / processes for update versus correction of data<br>It will be necessary to have workable process(es) for data correction in the functioning UPD; the policy should be amended to allow for this.<br><br>Looking at data correction, if the entry for U (Update) reads 'No', how are data corrections handled? Via EMA data stewards only? The latter are mentioned in footnote 4 for a specific reading role only.<br>From the regulators' side, for example, we assume NCAs can update an (initial) procedure number; the Agency cannot. Neither Agency nor NCAs can correct a marketing authorization date.<br><br>Similarly, from industry side, sales data can be "updated", but not dates of placing on the market. As regards post-authorization changes nobody can update Procedure Number, Variation Classification Codes or Submission comments. This may depend on the workflow; if it is a pure one-off process without any interaction, and any correction needs a restart, this may be fine. | According to Commission Implementing Regulation (EU) 2021/16, the holders of a marketing authorisation are responsible to notify the relevant competent authorities or the Commission, of any data quality issues identified in their products that are registered in the Union Product Database. In turn, the competent authorities or the Commission are responsible for correcting the data upon verification that the requests are justified.<br><br>Regarding the marketing authorisation date and the procedure number, the Annex has been amended to reflect that both fields can be updated by the Agency and the national competent authorities. Footnote 4 was specific to the field 'Nullification comment'. While the consultation on the access policy was open, it was decided in the project governance that the 'nullification comment' field will not be included in the UPD for the initial release and that its inclusion would be discussed and prioritised by the relevant governance in a future improvement release.<br>The field "Nullification comment" was been therefore removed from the Access Policy, as was the footnote.<br><br>As for the fields under section 'Procedural information for post-authorisation changes' in the context of the variations without assessment will not be editable by any of the stakeholders and it is confirmed that any corrections will require a restart of the process.<br><br>Finally, the date provided by the MAH where the product was marketed for the first time in a country will be considered as date of placing on the market. Therefore, the way in which they user will provide this value will be by filling in the fields availability status and availability status date. |

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| 7 | Judging by the C and U rights set MAHs are responsible to take care of small amount of data (sales, auth, status, some proc. Data in post-approval changes); this means everything else to enter will be in domain of CA and EMA. It was presented in such manner in 02-VMP-Reg Programme update; slide 2(CA should provide leg. data), CAs are responsible to enter data for initial MA and VRA. | This is correct, it will be the responsibility of the competent authorities and EMA to submit legacy data, create new products and applying any changes to product entries arising from post-authorisation regulatory procedures (such as variations) in the Union Product Database. |
| 7 | EGGVP welcomes the possibility to comment on the presented UPD access policy and appreciates early consultation.<br>However, EGGVP does not endorse the presented draft for the following reasons:<br>a. Information on data fields needed to handle variations not requiring assessment is missing. | The access policy captures all fields that Commission Implementing Regulation (EU) 2021/16 requires for the Union Product Database. It is noted that the list of variations not requiring assessment includes also such variations that would not have an impact on any field in the UPD, but these variations still need to be recorded in the UPD (procedurally) and accepted or rejected by the competent authority.<br>It is not foreseen to create data fields for all possible variations at this point in time, however addition of further fields can be considered in the prioritisation of potential improvements after the launch of the database in 2022. |
| 7 | b. To support transparency in regard to the period of protection of technical documentation (PTD – Art. 40 of regulation 2019/6), EGGVP suggests splitting the access rights of Level 2 into 2a (own products) and 2b (other products), as for example in Germany. This allows distinction of professional clients and the general public for fields related to variations, such as classification or date of submission/approval.<br>For further reference, see EGGVP position on this subject: | The access policy captures all fields that Commission Implementing Regulation (EU) 2021/16 requires for the Union Product Database. A field describing the end of the period of protection of technical documentation is not currently foreseen in the database, however addition of further fields can be considered in the prioritisation of potential improvements after the launch of the database in 2022. |

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| 7 | c. It is EGGVP understanding that the current draft does not support direct data entry / direct upload of documents from MAH IT systems into the UPD. The proposed process regarding variations not requiring assessment is a mere copy of the current process and with grouping no longer available for this type of variations it actually is an increase in administrative burden; hence failing the clear objectives of the NVR. | It is not foreseen that the first release of the UPD will provide direct data entry by the MAH in relation to the updating of both data and documents, but rather functionalities for submission of variations not requiring assessment and other post-authorisation data. Additional functionalities can be proposed for prioritisation in the ongoing improvements of the database from January 2022 onwards, in line with the process described in Article 2 (2) of Commission Implementing Regulation (EU) 2021/16. The access policy will subsequently be updated whenever the upgrades become available. |

## 2. Specific comments on text

| Stakeholder no. | Line No | Comment and rationale; proposed changes | Outcome |
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| 1 | Executive Summary line 44-46 | We understand that variations requiring assessment are included, but could you please confirm it? | Variations requiring assessment will not be processed in the UPD. For these variations the national competent authorities and the Agency will update the relevant product entry under their responsibility that already exists in the UPD, as required, following the end of the evaluation procedure. |
| 1 | Annex A line 265 | Proposal to change to subsequent recognition, according to Art. 53 of the NVR | Comment applied.<br>The wording "repeat use procedure" has been replaced by "subsequent recognition procedure". |
| 1 | Annex A line 265 | What does "nullification comment" mean in this context?<br>Could you please confirm that CA can create nullification comments but cannot read them? | Under certain conditions, a product that has been recorded in the UPD can be nullified by a national competent authority or EMA. The competent authority would be able to add a nullification comment, i.e. a comment that would explain this action.<br>While the consultation on the access policy was open, it was decided by the project governance that the 'nullification comment' field will not be included in the UPD for the initial release and that its inclusion would be discussed and prioritised by the relevant governance in a future improvement release.<br>The field "Nullification comment" was been therefore removed from the Access Policy. |

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| 6 | Annex A line 263 | Regarding public access to the authorisation status of veterinary medicinal products in the UPD, the Access Policy notes that "Only veterinary medicinal products that have been authorised will be shown". We believe that, on a safety basis, it would also be beneficial to list products that have been suspended and/or expired to ensure that these products are discarded. Public access to an active and visible directory is needed in case the person stocking the product has not been made aware of the public notifications. | Comment applied.<br>The General Public will have access to information on all veterinary medicinal products, whether they are authorised, withdrawn, suspended and revoked. However, this will not fully apply to legacy data, as national competent authorities are only obliged to submit legacy data for authorised veterinary medicinal products, so there can be no guarantee that legacy products with a status other than "authorised" will be available in the database at the time of the launch of the UPD in January 2022. |
| 4 | Sections 4.2.5.1.2 - 4.2.5.1.4 - 4.2.5.2 | In section „4.2.5.1.2. Methods of access" (line 195 – line 243) for all three access levels the personal data protection is described in a separate subsection like „4.2.5.1.4 Personal data protection requirements". In section „4.2.5.2 Marketing authorisation holders", a sub-section on protection of commercially confidential information of the same nature and value should be added. When using the term „commercially confidential information", the definition from the trade secret regulation (DIRECTIVE (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure) should be used. | As indicated under section 4.2.2. General Principles: "The VMP Regulation gives the widest possible access to veterinary medicinal product data and to the related documents while protecting certain public and private interests, such as personal data and commercially confidential information in accordance with Regulation (EC) No 1049/2001." The access policy is intended to restrict access by unauthorised users to fields that might contain commercially confidential information. Therefore, the suggested addition to the section 4.2.5.2 is not implemented in the document. |

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| 4 | Annex A | Annex A – Product data elements accessible by stakeholder group - describes the extent to which the data in the database may be handled. There is no possibility of correcting the data, supplemented by a corresponding audit trial. | According to Commission Implementing Regulation (EU) 2021/16, the holders of a marketing authorisation are responsible to notify the relevant competent authorities or the Commission, of any data quality issues identified in their products that are registered in the Union Product Database. In turn, the competent authorities or the Commission are responsible for correcting the data upon verification that the requests are justified. This is how information can be corrected. The Implementing Regulation also gives information on the related requirements for audit trails. |
| 8 | Annex A | FVE has some queries and comments on Annex A. The most important one we note is that 'clinical indication' is missing. This is a core element needed, without it veterinarians cannot properly use the database!!<br><br>For veterinarians, the most important information they need is:<br><br>- product name,<br>- qualitative and quantitative composition of the pharmacologically active substance(s),<br>- pharmaceutical form,<br>- countries the product is authorised in,<br>- SPC and PIL,<br>- clinical indications for use,<br>- target species and animal category,<br>- dosage for each species,<br>- method and route of administration,<br>- contra-indications and adverse events, | The access policy captures all fields that Commission Implementing Regulation (EU) 2021/16 requires for the Union Product Database.<br><br>In relation to the indications, the absence of harmonization among the different EEA countries and the lack of structured and controlled information significantly limits the benefit of including the respective field in the first release of the UPD.<br><br>Therefore harmonised translations of the field would not be possible at this stage and thus the search within this field would only return results in the respective language of the search, not supporting the objective of facilitating the single market. The inclusion of the field and associated limitations has been extensively discussed in the process of drafting the Implementing Regulation.<br><br>Given the great value this information would bring to veterinary healthcare professionals, it is suggested to initiate discussions on harmonising expressions of indication (for example short forms) to create controlled vocabularies that can be translated and subsequently prioritise inclusion in the Union Product Database in a future release. |

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| | | - drug-drug interactions,<br>- information essential for safety or health protection (e.g. precautions to the operator or to the animals),<br>- withdrawal time,<br>- distribution category,<br>- Marketing Authorisation Holder (MAH),<br>- therapeutic group,<br>- environmental precautions (e.g. around disposal of the product)<br>- And availability<br><br>The other elements listed in Annex A are welcome but should not prominently come up in the search in order to have an easy-to-consult user interface. In asking for this information it is also important that the each products listed is undoubtedly/uniquely identifiable. | Any other fields that might provide additional value to veterinary healthcare professionals can also be proposed for prioritisation in the ongoing improvements of the database from 2022 onwards, in line with the process described in Article 2 (2) of Commission Implementing Regulation (EU) 2021/16. The access policy will subsequently be updated whenever the fields available in the UPD change. |
| 8 | Line 74, 131, 144, 166, 187, 226, 232, 259 | Comment: Change term 'general public '<br>Proposed change (if any): change to 'Veterinary professionals and other interested persons' | Comment applied.<br>The term 'General Public' is used in both Commission Implementing Regulation (EU) 2021/16 and Regulation (EU) 2019/6 to refer to all persons or collectives that do not belong to the group of competent authorities, the Agency, the European Commission or Marketing Authorisation Holders. However, a clarification has been added to the section in the Access Policy where the Stakeholder groups are defined (4.2.1). |
| 8 | Line 187 | We welcome that in the third access layer search functions will be made available. It is important to have targeted, user-friendly search functions, which | The Access Policy defines the overall principles for providing access to veterinary medicinal product information held in the UPD and, while |

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| | | will be tested with the target audience. In addition, search should be possible on "key words" | the document mentions that search functions will be available to the general public, this policy is not intended to specify such functions. |
| 8 | Annex A, page 11 | • Indication should be added (authorised for which disease(s)/ condition(s), e.g. metabolic disorder or active against which microorganism, e.g. bacteria sp): this is vital! Veterinarians should also be able to search on a certain disorder or bacteria, e.g. search E.Coli & pigs or Salmon lice & salmon.<br>• Dose: the 'strength' of the formulation is mentioned but in the end the final dose determines the resulting 'exposure'. Of course this information is in the SPC/PL but when searching the database it's very convenient to have all this information at once to compare (instead of opening several different SPCs) → practical search/filter/select functions here again will be very important!<br>• Duration of treatment<br>• Target animal category → not only poultry but also 'broilers, layers.' etc. | The access policy captures only the fields that Commission Implementing Regulation (EU) 2021/16 requires for the Union Product Database.<br><br>In relation to the indications, the absence of harmonization among the different EEA countries and the lack of structured and controlled information significantly limits the benefit of including the respective field in the first release of the UPD.<br><br>Given the great value this information would bring to veterinary healthcare professionals, it is suggested to initiate discussions on harmonising expressions of indication (for example short forms) to create controlled vocabularies that can be translated and subsequently prioritise inclusion in the Union Product Database in a future release.<br><br>Any other fields that might provide additional value to veterinary healthcare professionals can also be proposed for prioritisation in the ongoing improvements of the database from 2022 onwards, in line with the process described in Article 2 (2) of the Implementing Regulation. The access policy will subsequently be updated whenever the fields available in the UPD change. |

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| 8 | Annex A, page 11 | Questions:<br>• Type of product: 'regular' or 'homeopathic' → is this accounted for via 'Product category' (p11)?<br>• Availability status → will this be on country level? Will it also indicate if the product is not available? | The 'Product category' field, currently named to 'Product type' in the final version of Commission Implementing Regulation (EU) 2021/16, is intended to identify the different types of veterinary medicinal products (VMP) that the UPD will store: authorised VMP, registered homeopathic VMP, VMP allowed for use in pets (Art. 5.6) and parallel traded products.<br>'Availability status' information will be provided at product level and will indicate whether the product is available (distributed by the Marketing Authorisation) in a particular Member State or not. |
| 2 | Table 2 - UPD system components with UPD product data outputs by stakeholder group | There is a need for a web user interface to data inputs (not all companies may be able to use Application Programming Interfaces). | Marketing authorisation holders will have at their disposal a web user interface that will allow them to fulfil all their legal obligations. More detail has been included in the Access Policy - section 4.2.4. Methods of providing access to veterinary medicinal product information held in UPD, where a new column for 'data inputs' has been introduced to the Table 2. |

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| 2 | Annex A | There is also a need to devise simplified procedures and take advantage of the potential of information technology. AnimalhealthEurope urges Regulators to take the opportunity to start implementing the ROG vision of database-only updates. Footnote (1) indicates that MAHs can request the update of some of the UPD fields, by the relevant Competent Authorities, via a variation that does not require assessment: hence, for example, a change of QPPV will have to go via a variation, although QPPVs are registered by a specific process in EudraVigilance. Similarly, in the case where a company changes its name due to a merger or acquisition, while remaining the same legal entity, a variation will be needed in addition to the OMS update. | It is noted that the update of several fields in UPD such as the ones mentioned in the comment can only be done by means of a variation not requiring assessment. This is a legislative requirement arising from Commission Implementing Regulation (EU) 2021/17. It is supported that the simplification of the procedures for these cases would be beneficial and is being considered in several forums, taking into consideration the legislative requirements. |
| 2 | Annex A | In Annex A, column MAH; it is not clear why for some data fields a footnote *6 = "Only visible to the MAH that owns that veterinary medicinal product", has been added (i.e. Annual Volume of Sales, QPPV Name, QPPV Location and the Procedural information for post-authorisation changes), and for some other data fields it has not been added (i.e. 'Manufacturing Sites' and 'Operation type (for manufacturing site)'). | Comment applied.<br>A new footnote has been added to the 'Manufacturing Sites' and to 'Operation type': "Only visible to the marketing authorisation holder that owns the relevant veterinary medicinal product, except for batch release manufacturing sites" |

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| 2 | 4.2.5.1 The Commission, competent authorities and the Agency | The role of "External Service providers" in the regulators stakeholder group needs to be clarified (for example their access rights, and their envisaged tasks). | As stated in the Access Policy, external service providers are considered "authorised personnel". Their access rights are administrated by the super user of the relevant organisation on whose behalf access is granted. The description of these roles and their related permissions will be incorporated to the UPD guide to registration which will be linked to the Access Policy. It is the assumption that access to any external service providers, whether they are associated with Marketing Authorisation Holders or regulators, will only be granted following establishment of appropriate contracts defining the responsibilities and confidentiality obligations of the external service provider. |

| Stakeholder no. | Line No | Comment and rationale; proposed changes | Outcome |
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| 2 | Table 2 - UPD system components with UPD product data outputs by stakeholder group | Data exchange including data input and data output<br>The scope of the policy should be clarified in respect of data input and output. In general, the policy seems to be addressing data output, that is access of stakeholders to data held within the UPD. However, the objectives (line 81) state that the policy 'has been developed with the goal of facilitating the maintenance of and accessibility to information on veterinary medicinal products in the EU'. Reference to 'maintenance' suggests the policy also applies to data input, therefore including access to upload data, in line with paragraphs starting at line 108 (data submission component), 112 (API) and 120 (VNRA component).<br>Therefore, logically and for completeness the policy should clearly state that it addresses both stakeholder access for data input (agencies and MAH) and output (agencies, MAH and public).<br>Section 4.2.4 (Methods of providing access to veterinary medicinal product information held in UPD) describes the UPD system components with UPD product data outputs by stakeholder group, however UPD product data inputs by stakeholder group are not described. It follows from the above that this information should be added. | Comment applied.<br>Section 4.2.4. Methods of providing access to veterinary medicinal product information held in UPD has been updated accordingly. |

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| 2 | 4.1 Union Product Database | Data input: Web portal<br>Paragraphs starting line 108 (data submission component), 112 (API) and 120 (VNRA component) clearly state that these permit the MAH to submit data into the UPD. However, paragraphs starting 118 (UPD portal) refers only to data export.<br>The web portal should give the possibility to the MAH stakeholder group to record information such as availability (which would not change frequently) and annual volumes of sales. There are two points here which are very important for MAHs:<br>• (1) There should be the option for MAHs to use a web based UPD portal for data submission, as SMEs (with only a few products) and some larger companies may not have the ability or wish to invest in linking to the UPD via an API; and<br>• (2) MAHs should have the ability to bulk load large datasets (e.g. annual volume of sales) through an appropriate system where MAH can generate a formatted file which the EMA can then import and use to populate the UPD. | The UPD will provide a web portal through which the MAH should be able to fulfil its legal obligations with respect to the Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16. In addition, appropriate mechanisms will be provided to the MAH to register large dataset such as the annual volume of sales. Further elaboration on the functionalities provided in the UPD is not within the scope of the UPD Access Policy, given that its objective is to define the overall principles for providing access to veterinary medicinal product information held in the UPD. |

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| 2 | 4.2.5.1.1<br>Line 195 | Security<br>A section explaining UPD safety features that prevent fraudulent access to confidential information would be welcome.<br>Line 195: 'External service providers are also considered "authorised personnel" '; we would appreciate clarification on the use of External Service Providers for the Commission, the Agency and competent authorities, in particular what tasks these providers may be requested to perform, measures in place to guarantee confidentiality of the data, and restrictions for accessing certain data types (for example sales data…). | The Commission, the Agency, the competent authorities and also the marketing authorisation holders can make use of External Service Providers (ESP), and in all cases they will be considered 'authorised personnel'. It is the responsibility of each of them to manage the ESP access rights and accordingly, to establish the appropriate mechanism to preserve the security of the data retrieved from the UPD (e.g. confidential/non-disclosure agreements).<br>In addition, the use of the API that will provide access to UPD data will be subjected to prior acceptance by the user of the EMA - API General Terms of Service - Terms of Use. In conformity to this document, it is responsibility of the user of the API to guarantee the protection of the data retrieved. |
| 2 | 4.2.5.2.1<br>Line 204 | It may be worth clarifying that companies that are part of the same corporation or group of companies are considered as a single MAH. | Each MAH will be associated with an OMS identifier defined by an organisation and the country in which it operates. In this sense, for each of these MAH's there will be a user responsible (super user) for administrating access rights according to certain roles or permissions. The super user may grant such permissions to users from the same organisations, both within the same country and from other countries, or to other users belonging to different organisations and also to external service providers. |

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| 2 | 4.2.5.2.3 | Access authorisation<br>The MAH should be able to provide occasional and limited access to any people working on a regulatory project, without access to the full MAH information in the database. | In the initial release of the UPD, the management of specific access is managed at organisation level, and do not allow to restrict the permissions to a subset of products. Following the initial release of the UPD, such additional functionality can be prioritised for inclusion in the Union Product Database in a future release in 2022 and beyond. Marketing Authorisation Holders are encouraged to establish appropriate internal procedures and contracts to limit the scope of work of specific users to a subset of product data, as needed, in the meantime. |
| 2 | Annex A | Documents (SPC, PL, PuAR)<br>MAHs should be allowed to update SPC/PL and manufacturing sites (necessary in the case of changes not requiring assessment); otherwise a clear process by which these updates can be achieved is required.<br>Additional proposal for MAH updateable fields<br>MAH should be able to update the following fields if it were accepted that a variation is not required (cf. ROG vision): PSMF Number, PSMF Location, QPPV Name, QPPV Location.<br>Example: update address of the release site (impacts manufacturing site data and on PL)<br>Example: update address of the release site (impacts manufacturing site data and on PL) | The UPD Access Policy is not detailing the specific functionalities of the UPD, but rather the overall principles for providing access to veterinary medicinal product information held therein. It is noted that both the Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16 envisage a specific process to update those fields that are subjected to change through variations not requiring assessment. |

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| 2 | Annex A | 'Manufacturing Sites' and 'Operation type (for manufacturing site)'<br>These should be only visible to the MAH that owns that veterinary medicinal product, except for batch releasing sites (= add footnote (6) to the Y in MAH column R). | Comment applied.<br>A new footnote has been added to the 'Manufacturing Sites' and to 'Operation type': "Only visible to the marketing authorisation holder that owns that veterinary medicinal product, except for batch release manufacturing sites" |
| 2 | Annex A | UPD fields for Procedural information for post-authorisation changes:<br>Fields 'Procedure Number', 'Responsible Authority', 'Variation Classification Code' and 'Submission Comment'<br>These elements should be taken from the eAF or its successor (or from the submission portal) – i.e. no manual data entry needed. | The access policy defines the overall principles for providing access to veterinary medicinal product information held in the UPD. It does not describe the technical functionalities, such as integrations with other systems or data sources. |
| 7 | Annex Manufacturing sites | Read-only access for MAHs not appreciated.<br>Change of UPD fields using API not possible this way.<br>It should be clarified if it is regardless of the interface (web or API) that MAHs won't be able to change data. | The information related to the Manufacturing sites will be updated in the Union Product Database following a variation not requiring assessment as provided by the Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16. Hence, this information will not be directly updated by the MAH in the product database, but rather updated by the competent authority as part of the acceptance of such a variation. |
| 7 | Annex - QPPV location | Read-only access for MAHs not appreciated.<br>Change of UPD fields using API not possible this way | The information related to the QPPV location will be updated in the Union Product Database following a variation not requiring assessment as provided by the Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16. Hence, this information will not be directly updated by the MAH in the product database, but rather updated by the competent authority as part of the acceptance of such a variation. |

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| 7 | Annex - Procedural information for post-authorisation changes | The UPD should provide transparency for marketing authorisation holders with regards to the expiration of the periods of protection of technical documentation (PTD). As such, a Level 2 split is needed. Possible example is Germany. Registered users: full access to own products, limited access to other products but more than general public. | The access policy captures all fields that Commission Implementing Regulation (EU) 2021/16 requires for the Union Product Database. A field describing the end of the period of protection of technical documentation is not currently foreseen in the database, however addition of further fields can be considered in the prioritisation of potential improvements after the launch of the database in 2022. |
| 7 | Annex Author of decision | If all groups have Read only access, who's populating the field? | The 'Author of decision' field belongs to the section 'Procedural information for post-authorisation changes'. This section was analysed in the context of the variations without assessment. In this case, the system will automatically record in this field the competent authority or the Commission making the decision (approve/reject), which will be derived from the user who is logged in. In case of variations requiring assessment, user intervention might be required to complete the field 'Author of decision'. The annex will be updated depending on the outcome of the design discussions on this field. |