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eAF (DADI)-PMS joint Q&A document

Electronic Application Form (eAF) and Product Management Service (PMS) Questions and Answers

Version 6

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of its release. The aim is to regularly update and rerelease this document. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, the eAF or the PMS teams.

Please note reference to the Digital Application Dataset Integration (DADI) Network project has been phased out in favour of eAF and Product Lifecycle Management (PLM) Portal.

For convenience, many technical terms are explained in the answers. In addition, there is a table of abbreviations at the back of this document.

For general inquiries, please contact the eAF team via esubprogofficer@ema.europa.eu and the PMS team via EMA Service Desk.

For questions or comments around the content of this Q&A document, please raise a ticket via the EMA Service Desk.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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ELECTRONIC APPLICATION FORMS (eAF)

eAF PRODUCT SCOPE

1. What will the eAF product deliver?

- The electronic Application Form (eAF) product, formally known as Digital Application Dataset Integration (DADI) Network Project, will replace current PDF-based electronic applications forms with new, web-based forms in a new dedicated portal. The web-based human variations eAF for centrally authorised products (CAPs) has been available for use as of 4 November 2022 on the Product Lifecycle Management (PLM) portal. Subsequently, eAFs for human and veterinary marketing authorisation applications, veterinary variations and human renewals will be replaced. Additional procedures will be considered.
- The web-based forms will:
    - Support both centrally authorised product applications at initial release of the forms and nationally authorised product (NAP) applications in subsequent releases for mutual recognition procedure (MRP), decentralised procedure (DCP), national procedures (NP) and, for veterinary, also subsequent recognition procedure (SRP). Additional forms for other procedure types will also be considered in future.
    - Standardise input for eAFs in order to effectively provide standard product master data for human and veterinary medicinal products.
    - Enable both the familiar human-readable (PDF) output and a new machine-readable output for digital processing based on the Fast Healthcare Interoperability Resources (FHIR) data exchange standard for medicinal products. The PDF rendition will be generated from the web User Interface (UI) and it will contain both the PDF document and an attached FHIR Extensible Markup Language (XML) (ref. Question 21).
    - Use available product master data from Product Management Services (PMS) for human and the Union Product Database (UPD) for veterinary medicinal products to prepopulate form fields where relevant.
- The eAF will *not* change:
    - The process to apply for or submit marketing authorisation applications.
    - The format of the current PDF output.
    - The content of the output form included in the application, changes to which are not governed by the eAF team.

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eAF PRODUCT BENEFITS

2. What are the main benefits that the web-based forms will bring?

- The web-based forms will replace aging technology considered no longer fit for purpose, thus enabling progressive usability improvements for users over the current PDF forms through integration with PMS/UPD data. For example, the new forms will help applicants' form filling by using available PMS/UPD data to prepopulate form fields where relevant (product selection and structured product data, where available).
- User-friendliness will improve over time as all the standardised Product and Substance Management Service databases become available, for example substances drop down lists will take much shorter time to load and will have less duplicate or confusing entries.
- The new forms are a means to enable more efficient application processing, reducing administrative burden. For example, the forms will support validation of applications by competent authorities, reducing errors and discrepancies.
- The forms will facilitate standardised, structured data being fed into databases making interoperability of systems and sharing of data between competent authorities much easier.

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eAF PRODUCT ROADMAP

3. Why is the eAF product running now?

- Work on replacing the electronic application forms with forms that would support efficiency and better interoperability was first undertaken as part of the Common European Single Submission Portal (CESSP) Phase 1 project started in 2016 and stopped in 2020.
- The need to replace the forms and align Industry-facing applications has only increased since then, as the current Adobe PDF eAFs are aging, and risk no longer being fit for purpose.
- Momentum, relevant expertise and know-how built up during the CESSP Phase 1 project were capitalised by the former DADI Network project. That is also the case with expertise on the technology chosen for the new web-based forms, which is the same as the IRIS Portal.
- In line with EMA's phasing into an Agile way of working and governance model for IT systems and services, the DADI Network project successfully piloted the Agile methodology and subsequently transitioned into the eAF product. Product ownership of the web-based forms is shared between EMA and NCA representation, which means requirements gathering and design is done collaboratively between EMA and the Network.

- Improvement of EMA's core processes is dependent on delivery of new forms facilitating standardised data entry for CAP applications. The data captured in forms is the entry point for data used throughout EMA's own core processes which are a key area for improvement over the coming months and years.
- The "Up-scaling the global univocal identification of medicines" (UNICOM) Horizon2020 project received funding to foster the implementation of ISO IDMP and the usage of SPOR (Substances, Products, Organisations and Referentials) in the European Regulatory Network by 2023.
- In the context of the application form, seven NCAs members of the European Medicines Regulatory Network are working together with EMA experts: AGES (Austria), BfArM (Germany), AEMPS (Spain), HPRA (Ireland), MEB-CBG (the Netherlands), NOMA (Norway) and SE MPA (Sweden).

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4. What are the next steps for eAF deliverables?

- The first release of the variations web-based eAF for human medicinal products took place in November 2022. The form is being further improved and expanded in subsequent releases. This progressive release model follows the Agile development model of the Agency.
- The scope of the first release of the human variations web-based eAF was limited to CAPs. This version of the form cannot yet be used for applications containing NAPs, including National Procedures, Mutual Recognition Procedure and Decentralised Procedure.
- The start of PMS data transfer will trigger optional use of the web-based human variations eAFs for NAPs as these products become available on the PLM Portal.
- The expected release order of forms after human variations will be confirmed at a later stage.
- The variations form for human medicinal products was tested through closed User Acceptance Testing (UAT) with members of the eAF Subject Matter Expert (SME) Group, which were followed by testing of the PMS data (through a PMS UAT) that the forms will use.
- Finally, external User Acceptance Testing focused on CAPs with a larger, but still limited, group of testers took place from 19 September to 30 September 2022. Participation was mainly for Industry as, at that time, NCAs could not test the portal, but were requested to look at the PDFs generated by the Industry testers. A second UAT involving Industry and NCA participants focused on the version of the web-based eAF intended to replace the PDF and trigger the transition will follow. Functionalities required for mandatory use are being released incrementally: all required functionalities will be available on the PLM Portal before the start of the UAT.
- Pending a successful outcome, the UAT will be followed by a 6-month transition period to mandatory use of the web-based eAF, during which users will have the possibility to use the PDF eAF as a backup.

- At the end of the transition period, the use of the web-based form will be required. The use of the web-based eAF will follow the current process for updating data. Use of structured data will be implemented at a later point.
- Further details on User Acceptance Testing and subsequent development on other forms will be shared on a regular basis during the coming months.
- Communications around timeline are published on the PLM Portal Forum and the PLM Portal eAF page of the eSubmission website.

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5. Will there be User Acceptance Testing for eAF?

- Yes, User Acceptance Testing aims at verifying that the requirements pertaining to the human variations web-based eAF have been met. During the UAT phase, users have the opportunity to test and provide feedback before an official release of the PLM Portal, by covering as many real-world scenarios as possible.
- The UAT approach for the human variations web-based eAF comprises the phases below:
    - Internal testing (sprint and Alpha UAT), and,
    - External testing (Beta UAT).
- Internal testing is performed throughout the development sprints (according to the SAFe (Scaled Agile Framework) methodology) and assesses the subsequent developed functionalities of the human variations web-based eAF. Internal testing consists of sprint UATs - performed by EMA staff – and where relevant also Alpha UATs - performed by a selection of volunteers from the eAF SME Group. The SME Group includes Subject Matter Experts from EMA, NCAs and Industry and represent those respective stakeholder groups.
    - As part of the Internal testing, regression testing is also performed. This is particularly relevant to test the successful synchronisation of the product data from PMS. The data testing is not in direct scope of the eAF product; however, it is a critical dependency.
- External testing, or Beta UAT, tests the eAF's functionalities and (PMS) data together. The purpose is to facilitate testing by a wider group of testers and to cover the most likely scenarios for different stakeholders.
    - The first Beta UAT took place from 19 to 30 September 2022. A call for volunteers to participate in the first Beta UAT was launched between 7 -15 July 2022.
    - The users have been able to use and to familiarise themselves with the new tool for CAPs since the first release of the PLM Portal, on 4 November 2022.
    - Further to that, a second Beta UAT will aim to test the version of the web-based eAF intended to replace the PDF and to trigger the transition period.
- In addition to testing, the eAF team will demonstrate the new forms in one or more public webinars closer to their release dates. Similar events will be

organised in the future to demonstrate new functionalities as they are ready for release.

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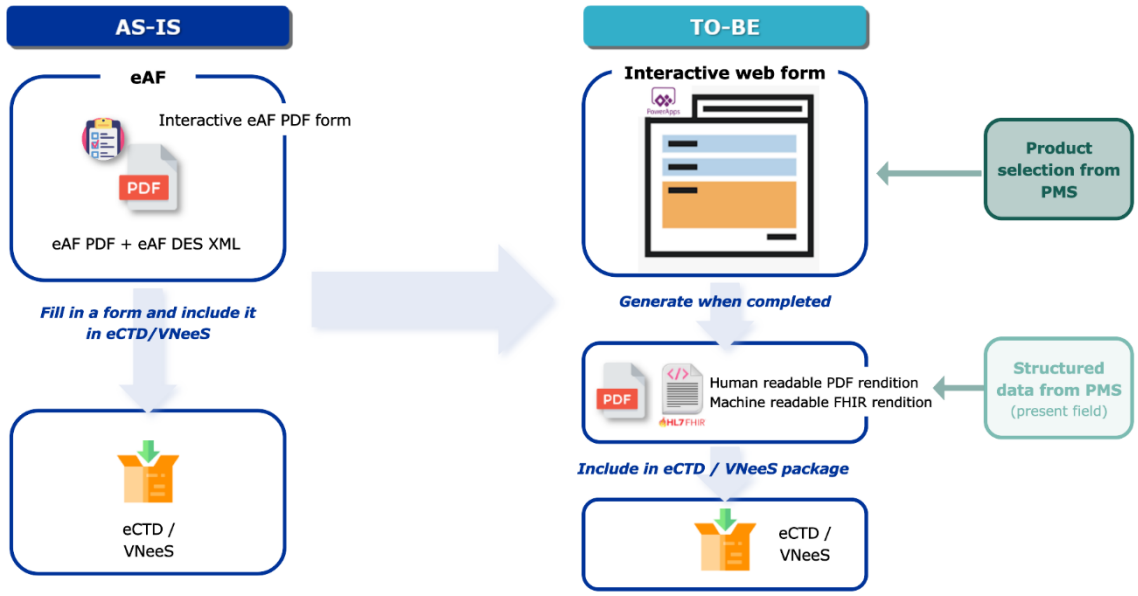
eAF WEB-BASED FORMS

6. What will change technically in the forms?

- Applicants will fill out a web-based form instead of an interactive PDF form.
- The output, which the regulators will receive as part of the submission package, will include both the familiar human readable PDF document and an attached FHIR message which can be read and processed by IT systems.
- Submission of web-based human variations eAFs will not differ from submission of the current eAFs.
- See Diagram 1 below for a visual description of technical changes:

Diagram 1 – Current situation vs future situation for eAFs



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7. Which will be the options available to create the PDF eAF in the new interface?

- Three options were considered by the eAF team:
  - Using the web-based form to create applications and export to PDF with an attached FHIR message;
  - Creating the entire application FHIR message in an applicant's own system to submit to an Application Programming Interface (API) for validation and transformation into a PDF with attached FHIR message;
  - Importing a partial FHIR message into the web-based form to complete the application in the web User Interface.

- Of these three options, the first is what has been available upon initial release. This is the core feature of the web-based forms which enables a move away from the current PDF-based data input while also enabling the FHIR output attached to the PDF output to facilitate handling of applications.
- The second option is undergoing further analysis and design work to ensure validation of data provided through such a mechanism can be ensured. The third option is pending a technical feasibility analysis.

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8. Will the content requirements for the application form change?

- The web-based forms are the input forms to create the application, these will change to accommodate PMS/UPD data requirements.
- The output PDF rendition of the forms looks very similar to the current PDF eAF and has the same information as the current forms.
    - It should be noted that some of the current footnotes may not be relevant anymore, however, as they are part of the Notice to Applicants (NtA) form, they cannot be removed from the PDF rendition. For example, the reference to mandatory signature in the PDF can be ignored for the time being when the eAF is generated from the PLM Portal.
- In addition, the FHIR XML backbone may contain additional metadata to facilitate regulatory activities.
- Details on all changes in data requested in the web-based form compared to the current eAF will be shared as part of the implementation and roll out.

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9. Is registration required to fill in an eAF? Is there any guide for consultancies?

- Every person involved in the drafting of an eAF must have an EMA account and (at least) an eAF role assigned to that account.
- Each Marketing Authorisation Holder (MAH) should ensure that consultants working on their behalf obtain an EMA account and an eAF role, so they are allowed to work with/edit an eAF. Different roles grant different access privileges. The implemented access management logic allows for two different types of consultant access: access to all products from that MAH (eAF Applicant Managers or Coordinators) or access to specific applications containing products (eAF Applicant Contributors).
- In case of co-authoring, it is suggested to coordinate well with contributors, as there is the possibility of overwriting data if multiple people work on the same section simultaneously.
- For more information on access management, please consult the PLM Portal (eAF) guide to registration.

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10. Does the form need to be signed?

- The web-based form contains the fields for the name of the signatories.
- It is strongly recommended to sign the exported PDF form using a digital signature. However, EMA is currently not reinforcing the signature requirement and applications without signature are being accepted. The mandatory requirement for a signature is still under discussion.
- Alternatively, the exported eAF can also be signed using any Adobe signature tool or by adding an image of a signature.

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11. Will the web-based forms still be called eAFs?

- The expectation is that the web-based forms will still be called electronic application forms (eAFs).
- In its communications, EMA will frequently refer to web-based application forms to distinguish them from the current PDF format electronic applications forms. Technically, both are electronic application forms.

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12. Will the eAF product deliver forms complying with the new Veterinary Medicines Regulation (Regulation (EU) 2019/6)?

- Veterinary forms are in scope for the eAF product. This means that when web-based forms for veterinary medicinal products that will be released must comply with the Veterinary Medicines Regulation (Regulation (EU) 2019/6).
- Due to the regulatory risks and the development risks of the form, the former DADI Network Project Steering Committee decided to decouple the development of the veterinary variations web-based form from the regulatory deadline of 28 January 2022. Instead, the PDF format variations electronic application form was updated to support regulatory requirements for the 28 January deadline.
- The main benefit of this approach was a reduced risk of new technology disrupting the transition to the new regulatory requirements. In addition, it means that a transition period can be facilitated, which will benefit from lessons learned from rolling out the human variations form.
- Development work on the veterinary web-form will start at a yet to be determined time.
- In the meantime, veterinary representatives participating in the eAF SME Group have been invited to stay on as observers to ensure a smooth uptake of veterinary requirements once development starts.

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13. What is the connection between the web-based forms and UPD for veterinary medicinal product data?

- The UPD refers to the requirement for a new Union Product Database for all authorised veterinary medicinal products as per the veterinary medicinal products regulation, EU Regulation 2019/6. The UPD is accessible to the general public and will be a searchable database.
- UPD uses the same data repository for product master data as PMS, and it is commonly referred to as UPD to distinguish it from product master data for human medicinal products.
- The new web-based forms will standardise input for eAFs in order to effectively provide standard UPD data.
- The web-based forms will also use available UPD data to prepopulate form fields where relevant.
- FHIR was selected as the application programming interface for the common PMS and UPD data repository and the web-based forms are an example of FHIR being used to read data from the application programming interface and display it in the web-based forms.

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14. Who will maintain the new web-based forms?

- The system facilitating the forms will be technically maintained and supported by EMA.
- The EMA Service Desk will be available to address issues and there will continue to be opportunities for applicants and other stakeholders to propose features.
- Until further notice the existing eAF Maintenance Group, which plays a key role in maintaining the current forms as well as providing expertise on the new, web-based forms, will continue.
- As part of the eAF product, the governance will be reviewed, transparently, with the expectation that a subject matter expert body, such as the current eAF Maintenance Group, will continue to exist with EU Regulatory Network and Industry representation.

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15. Will the use of web-based forms be mandatory for CAPs and NAPs at the same time?

- The use of the variations web-based forms will become mandatory for both CAPs and NAPs at the end of the transition period.

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16. Will all products (CAPs and NAPs) be searchable within the eAF from the first release?

- No, the first release of the variations web-based eAF supported CAPs only. With the start of data transfer, the first NAPs will appear in the eAF. This will allow users to start preparing web-based eAFs for NAPs as these products become gradually available on the PLM Portal. All products (CAPs and NAPs) will be searchable according to access management rules upon completion of the data transfer.

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17. Are the forms still owned by the NtA group?

- Yes, for human medicinal products the European Commission Notice to Applicants (NtA) Expert Group will remain responsible for the content requirements of the application forms.
- The web-based forms will meet these content requirements. They will however also ask additional information to support efficient handling of applications and SPOR data management services.

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18. How will stakeholders be notified of future changes to the forms?

- The web-based forms will support both Centrally and Nationally Authorised Products applications – requiring some coordination around updates and changes.
- The PLM Portal release notes describing changes and updates (such as bug fixes and new features) are published at the time of each production deployment on the PLM Portal and in the eSubmission website to ensure users are aware of the changes impacting the system.
- Other news, updated user guidance documents and relevant details and artefacts are also available from the PLM Portal and eSubmission website.
- The change control and maintenance processes are part of eAF deliverables. However, they have not been agreed yet at this time.

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STAKEHOLDERS

19. How is the eAF product taking stakeholder perspectives into account?

- The eAF product addresses both Centrally Authorised Product Applications and Nationally Authorised Product Applications.

- The eAF product has established a Subject Matter Expert Group (formerly known as the DADI Requirements Group) which represents Subject Matter Experts from EMA, NCAs and Industry. Participation to the group is limited.
- The SME Group meets on a weekly basis and provides expert insight into the use of forms, as well as input for EMA requirements for CAPs and NCA requirements for NAPs.
- The SME Group is also involved in testing of the forms.
- Planning and implementation are following SAFe Agile principles. Product ownership of the web-based forms is shared between EMA and NCA representation, which means requirements gathering and design is done collaboratively between EMA and the Network.
- Product ownership for NCAs is an in-kind contribution of the UNICOM Consortium.

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20. How is UNICOM contributing to the eAF product?

- UNICOM is a European Commission (EC) Horizon2020 funded consortium separate from the European Medicinal Regulatory Network's IT governance structure.
- Two of its objectives relate to ensuring the availability of Pan-European IDMP Compliant forms (Work Package 3) and IDMP implementation at National Agencies (Work Package 4). UNICOM has an inbound dependency on the eAF product for Work Package 3.
- UNICOM provides in-kind contributions to the eAF product work and the web-based forms for among others: a Product Owner, communication and training to NCAs and applicants, supporting NCAs to automatically import form data, liaison with the Notice to Applicants Expert Group, contributing to UAT and IT development for FHIR messages and PDF representations for NCAs.
- EMA has no contractual obligations towards the UNICOM Consortium and the European Commission.

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21. How will the eAF product impact Competent Authorities?

- The web-based application forms will be common for both NAPs as well as CAPs which are processed by NCAs and EMA respectively.
- The forms impacted are used in NCA relevant authorisation procedures:
  - mutual recognition procedure (MRP);
  - decentralised procedure (DCP);
  - national procedure (NP);
  - subsequent recognition procedure (SRP) for veterinary.
- The web-based forms create opportunities to automate manual processes related to processing forms and facilitate the collection of standardised data.

- Competent authorities that are not currently using the PDF forms' Extensible Markup Language (XML) functionalities will notice little change – the PDF output of the web-based form may look a little different.
- Competent authorities currently using the PDF forms' XML functionalities will need to adjust their systems to accommodate the new FHIR compliant XML.

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22. How will the eAF product impact industry stakeholders?

- The current PDF format variations eAF will be replaced by a web-based user input form for CAPs and NAPs applications. After the initial release on 4 November 2023, the web-based form supports CAP applications only. Subsequently, the form will support all types of EU variation procedures (CAPs and NAPs).
- Any new web-based application form will be prepopulated with available PMS/UPD data. Industry will have visibility of data available on the regulator's side.
- The forms will support the collection and use of standardised PMS/UPD product master data.

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TRAINING

23. Will there be training?

- As part of the roll-out of the new forms, a learning offering will be made available approaching their release.
- EMA and NCAs have been cooperating to provide support, guidance and training for applicants ahead of the roll-out of the first form (variations) and following its release.
- In addition, several webinars have been delivered to support roll-out and answer questions from applicants and stakeholders. Please consult the PLM Portal Forum and eSubmission website to remain up-to-date with upcoming webinars and Q&A sessions.
- User guides have been developed and are continuously updated to fully support the web-based forms. Interested stakeholders can access the PLM Portal (eAF) guide to registration and guide to navigation from the PLM Portal Forum and eSubmission website.
- A Frequently Asked Questions (FAQs) document based on questions frequently asked during the human variations eAF Q&A Clinics has been developed by the eAF and PMS team and will be updated on a regular basis. Additionally, users can rely on the PLM Portal chatbot and PLM Portal Forum to ask their questions. Please note any text contained in the threads of the

forum is publicly available, therefore users are invited not to post any type of confidential information.
- There will be help online and on-screen tooltips within the system.

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PLM PORTAL & IRIS

24. What is the difference between the PLM Portal and IRIS?

- IRIS is EMA's online platform to support product-related scientific and regulatory procedures with EMA.
- The PLM Portal will host application forms for all EU procedures (CP, MRP, DCP, NP, SRP). After filling in the web-based form, the applicant will generate a PDF which is submitted through existing eSubmission channels as part of eCTD package.
- IRIS and the PLM Portal serve different purposes and will be governed differently. However, the intention is to facilitate and develop ease of use across the two portals wherever feasible.
- IRIS is implemented using several technologies that are also used to deliver the PLM Portal, i.e., Microsoft PowerApps. Experience gained by EMA in building IRIS is helping to implement the PLM Portal.

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ISO-IDMP & DATA

25. What is ISO IDMP?

- The International Organisation for Standardisation (ISO) standard for identification of medicinal products (IDMP).
- ISO IDMP specifies the use of standardised definitions for the identification and description of medicinal products for human use.
- Their purpose is to facilitate the reliable exchange of medicinal product information in a robust and consistent manner.
- They help to ensure wide interoperability across global regulatory and healthcare communities, which is critical in ensuring accurate analysis and unambiguous communication across jurisdictions.
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges EU Member States, MAHs and EMA to make use of the ISO IDMP standards. This will impact on many areas of the pharmaceutical regulatory environment, both in the EU and other regions.
- For more information, see this Introduction to ISO IDMP and SPOR.

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26. Will the data requested in forms for human medicinal products be ISO IDMP-compliant?

- The intention is to facilitate exchange of standardised master data, therefore, the forms will use PMS data which comply with ISO IDMP standards for human medicinal products.
- The scope of ISO IDMP and SPOR is different: ISO IDMP covers the entire medicinal product lifecycle, including development, while PMS in SPOR covers only the Authorised Medicinal product part of IDMP.
- ISO IDMP covers human medicinal products only.
- See this presentation for further details on the relation between SPOR, ISO IDMP and FHIR.

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27. Will it be possible to download/export products data from the web User Interface?

- The users will be able to see the relevant product data via the web UI and download the forms which contain such data. However, there will be no dedicated capability neither to export only product data nor to perform bulk exports in the eAF web UI.

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FHIR

28. What is FHIR?

- Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging healthcare information electronically.
- The eAF team will create a FHIR specification as backbone for each of the new web-based forms.
- FHIR is the machine-readable language chosen to support the easy exchange of data between web-based forms, systems and product databases such as PMS and UPD.
- FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications.
- The basic building block in FHIR is a Resource. All exchangeable content is defined as a resource. Resources all share the following set of characteristics:
    - A common way to define and represent them, building them from data types that define common reusable patterns of elements;
    - A common set of metadata;
    - A human readable part.

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29. How will the eAF FHIR message relate to the PMS/UPD messages?

- The eAF FHIR message comprises two major parts: (1) the procedure part, known as the task resource, and (2) the medicinal products part. The procedure part is eAF specific, while the medicinal products will be represented through FHIR resources which match those of PMS and UPD.
- A resource is the basic building block in the FHIR standard. All exchangeable content is defined as a resource. Resources all share the following set of characteristics:
    - A common way to define and represent them, building them from data types that define common reusable patterns of elements;
    - A common set of metadata;
    - A human readable part.
- There may be some additional resources and elements in the product part for the eAF that are needed only for a given regulatory procedure i.e., not to be reused. These will not be entered into PMS or UPD.

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30. Will the mapping of the FHIR resources used by eAF with IDMP be published?

- The medicinal product resources used in common by PMS and the web-based eAF have the same name, so users can look for them in PMS EU IG Chapter 2. The FHIR resources have the mapping to IDMP present in FHIR already (e.g., http://hl7.org/fhir/2021May/medicinalproductdefinition-mappings.html).

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31. Will the FHIR message that is embedded in the web-based form PDF export be used to update PMS?

- This did not happen at the go-live of the human variations eAF, and submissions to Art. 57 are still needed. In the future, the idea is to use the data provided in the variations web-based form in order to update the data in PMS.
- However, the FHIR XML is used to automatically feed the EMA's procedure management system with the information from the application form.

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32. Is an HTML FHIR viewer publicly available?

- Proprietary tools to transform FHIR XMLs to HTML are publicly available.

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SPOR

33. What is SPOR?

- SPOR is an acronym used to refer to the four domains of pharmaceutical master data: Substance, product, organisation and referential (SPOR) master data.
- The EMA and the European Medicines Regulatory Network agreed to implement the ISO IDMP standards for the identification of medicinal products in a phased programme, based on these four domains of master data in pharmaceutical regulatory processes.
- More information related to SPOR can be found in Substance, product, organisation and referential (SPOR) master data | European Medicines Agency (europa.eu)

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Product Management Service (PMS)

PMS SCOPE

34. What is PMS?

- PMS is the Product Management Service for product master data for human medicinal products. It is one of the four data management services for human and veterinary medicinal products known as SPOR (substance, products, organisations and referentials). For Veterinary medicinal products, the Union Product Database (UPD) is the service through which product master data is provided.

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35. What will PMS deliver?

- PMS makes available comprehensive and consolidated data on CAPs and non-centrally authorised products (non-CAPs) from different sources across the European Medicines Regulatory Network, that is structured, standardised, authorised to be used by regulators and industry in regulatory and non-regulatory procedures, as well for the general benefit of European citizens.
- PMS enables the implementation of globally recognised ISO standards for the identification of medicinal products (IDMP).
- The PMS implementation process is iterative, in steps. The first iteration of the PMS will cover a subset of the authorised **medicinal product** part of the ISO IDMP standards. As part of this iteration, the new ISO IDMP compatible data submission format (HL7 FHIR) replaces the current data submission format, the eXtended EudraVigilance Product Report Message (XEVPRM).
- Future PMS iterations will implement other product data elements of the authorised medicinal product and the investigational medicinal product part of the ISO IDMP standards.

PMS BENEFITS

36. What are the main benefits of PMS?

- PMS is an implementation of globally recognised ISO standards for the identification of medicinal products (IDMP). Through this, PMS allows everyone to align to one standard set of rules for product data. That enables the exchange of interoperable data, greatly facilitating processes of many different data users including administrative processes of regulators.
- PMS specifically creates process efficiencies by delivering comprehensive and consolidated medicinal product data (CAP and non-CAPs) from different sources which can be re-used in electronic applications and throughout

regulatory processes. Assessment as part of the regulatory procedure can come to use commons, standard data, removing much of ambiguity and interpretation of data during the assessment.

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PMS TIMELINE

37. When will PMS be delivered?

- The PMS product will be delivered in multiple releases. Each release will either add or improve features. PMS will release both standalone as well as part of other IT products, such as electronic applications.
- The migration of CAP medicinal product data from the EMA database (SIAMED II) has been delivered in May 2021. PMS makes available CAP data in ISO IDMP compliant format, as per dossier business rules and validated by EMA.
- CAP medicinal product data provided by PMS is already used internally by EMA to support the manufacturer audit process. The first release of the human variations web-based eAF also relied on CAP medicinal product provided by PMS.
- The migration of medicinal product data from XEVMPD is ongoing and in by the end of Q2, beginning of Q3 2023, PMS will also contain NAP products.
- Future releases of PMS will:
    - Allow Industry to access, see and export the data in PMS;
    - Enable pharmaceutical companies to correct and complete PMS product data;
    - Enable data approved within a regulatory application to be stored in the PMS;
    - Ensure adequate data quality in the PMS so that it can be confidently reused across procedures;
    - Replace Art. 57 submission process, data format and data content.

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38. When will the User Interface be delivered?

- At the moment, there is no User Interface to check the data in PMS, and the only way to see product data is through the PLM Portal eAF, where specific product data coming from PMS is shown.
- EMA is working on developing and releasing a User Interface.
- EMA will communicate the date when the User Interface will be made available for use in due course and via the official EMA Agile channels.

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PMS DATA

39. What will happen to XEVMPD?

- XEVMPD is the current database used by Industry to submit and maintain product data (both CAPs and non-CAPs). This data is used by EMA and NCAs for several processes.
- Continuity of these processes is important and therefore until a full migration to PMS is feasible, XEVMPD will be maintained.
- EMA is working to guarantee that duplicate submissions to PMS and XEVMPD by Industry will not be necessary and in due course the new ISO IDMP compatible data submission format (HL7 FHIR) will replace the current data submission format, the eXtended EudraVigilance Product Report Message (XEVPRM).
- Until further notice the current process for submission of product data to XEVMPD should be used.

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40. Where does the data in PMS come from?

- For the first release of the web-based forms which support CAP products only, the data in PMS comes from SIAMED II. SIAMED II is the internal EMA database where CAP product data is stored and maintained. EMA migrated product data from SIAMED to PMS. All the information related to this migration exercise can be found in Chapter 7 of the EU IDMP IG.
- For the release of both CAPs and non-CAPs in the PLM Portal, XEVMPD data will also be migrated to PMS. XEVMPD data is provided and maintained by MAHs for both CAPs and Non-CAPs. Chapter 7 of the EU IG was updated to provide all the information on the business rules used by EMA to migrate the data from both sources, i.e.: SIAMED II and XEVMPD.
- For the time being, any update to product data done in SIAMED II or XEVMPD will also be reflected in PMS.

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41. What are XEVMPD to PMS deltas?

- XEVMPD to PMS deltas are used to update PMS whenever there is an update on XEVMPD. In this way, PMS will be kept up to date until direct submissions are available in PMS. More information on this topic is available in EU IG Chapter 9.

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42. How long will it take between updating XEVMPD and seeing the amended data in PMS?

- EMA will process the deltas almost in real time. Nevertheless, as soon as the XEVMPD data is migrated and the deltas are captured by PMS, the performance might not be the desired one. Indeed, the deltas are sent to a queue and are processed in that order. This means that changes performed in XEVMPD might take some time to appear in PMS. EMA is working to improve the performance.

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43. How will I see data in PMS?

- PMS team will provide a User Interface where users will be able to see the data available in PMS.
- The PMS roadmap also plans to create API connection for users that prefer to connect their internal systems to PMS.
- For the time being, as the User Interface and the API connection are not available, products from PMS can only be seen through the PLM Portal.

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44. Will NCAs validate PMS data?

- A decision on this matter is pending, and further discussions with NCAs and Industry stakeholders are required. Additional information will be provided in due course.

45. How do I correct or complete my data in PMS?

- If data found in PMS originating from XEVMPD is wrong or not up to date, users can submit updates through XEVMPD to amend data in PMS. In case the source of information is SIAMED, a process will be established and shared with the stakeholders.
- EMA is working on releasing a User Interface and API connections to allow users to correct and/or complete missing data in PMS. The process and timelines for these corrections/enrichments is still under discussion. More information will be shared in due time.

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PMS & eAF

46. What is the difference between eAF and PMS?

- PMS is the Product Management Service for product master data for authorised human medicinal products. It is one of the four data management services for human and veterinary medicinal products known as SPOR

(substance, products, organisations and referentials). For Veterinary medicinal products, UPD is the service through which product master data is provided.
- eAF refers to the IT product that replaces the PDF-format eAFs with new web-based forms.
- PMS will be the means to:
    - Standardise input for eAFs to effectively provide standard product master data for human and veterinary medicinal products.
    - Use available product master data to prepopulate form fields where relevant.

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47. How is PMS go-live impacted by web-based form releases?

- PMS go-live, i.e., its first public release, is linked to the web-based form release calendar, as variations forms for human medicinal products are the first publicly available system consuming data from PMS.
- NAPs data release is also supporting the variations web-based forms for non-centrally authorised medicinal products.
- PMS team is nevertheless working to deliver other capabilities and enablers needed to support PMS.

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PMS IMPLEMENTATION GUIDE

48. What is the PMS Implementation Guide and which is the latest available version?

- The PMS EU Implementation Guide for the submission of data on medicinal products defines the implementation requirements of the ISO IDMP standards and will be the basis for submission and exchange of medicinal product data in the EU.
- The PMS EU Implementation Guide is updated on an as needed basis when enough material changes merit updating the document. The latest update dates back to January 2023, when version 2 of Chapter 7 was published.
- Future releases of the EU Implementation Guide will be announced in advance and follow appropriate stakeholder consultation procedures.

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STAKEHOLDERS

49. How is the European Medicines Regulatory Network involved in PMS?

- PMS addresses both Centrally Authorised Product and Nationally Authorised Products.
- The PMS governance is shaped along Agile software development and portfolio governance principles: the PMS product team has established a Subject Matter Expert Group with Subject Matter Experts from the Network and Industry in order to bring insight and expertise from all users of PMS to the table.
- The SME Group meets on a weekly basis and provides expert advice to the PMS Product Owners.
- The SME Group is also involved in testing of PMS before releases.
- Product ownership of PMS is shared between EMA and NCA representation, which means requirements gathering and design is done collaboratively between EMA and the Network.

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50. How is Industry currently consulted in PMS development and implementation?

- The EMA works closely with Industry stakeholders and its partners in the European Medicines Regulatory Network to guide strategic priorities and ensure that the EMA's IT development portfolio creates the optimal value for all stakeholders.
- At the strategic and portfolio level Industry is engaged through the Strategic Portfolio Review ceremonies. Additionally, EMA Executive Board has bilateral meetings with Industry on an annual basis.
- At the execution level, the EMA has established a Subject Matter Expert (SME) Group for PMS, including Industry SMEs, which provides expert insight and advice to the PMS Product Owners and is closely involved in the solution design.
- The PMS SMEs and Network Product Owner succeeded governance as originally established for SPOR.

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HELP

51. My question is not answered here, what do I do?

- Work on eAFs and PMS is still ongoing, therefore not all questions have definitive answers. As topics are clarified the eAF and PMS teams will share

details and supporting documentation, including updates to this Q&A document.

- Applicants wondering about specific features and interests can consider contacting an industry association representative on the SME group or contacting EMA directly.
- For general inquiries, please post your question in the PLM Portal Forum or contact the eAF team via esubprogofficer@ema.europa.eu. For questions or comments around the content of this Q&A document, please raise a ticket (by selecting "Ask a question" and including in the subject "eAF-PMS Q&A") via the EMA Service Desk.
- If you have a technical question about the current eSubmissions systems or the eAF product, please raise a ticket (by selecting "Ask a question" and including in the subject "eAF") via the EMA Service Desk.
- If you have any question related to PMS, please raise it via the EMA Service Desk.

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Table of abbreviations

AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AGES	Austrian Agency for Health and Food Safety
AMP	Authorised Medicinal Product
API	Application Programming Interface
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAP	Centrally Authorised Product
CESSP	Common European Single Submission Portal
CP	Centralised Procedure

DADI	Digital Application Dataset Integration
DB	Database
DCP	Decentralised Procedure
eAF	Electronic Application Form
eCTD	electronic Common Technical Document
EV Code	Eudra Vigilance Code
EEA	European Economic Areas
EC	European Commission
EU	European Union
EMA	European Medicines Agency

EMRN	European Medicines Regulatory Network
FHIR	Fast Healthcare Interoperability Resources
H	Human
HL7	Health Level 7
HPRA	Health Products Regulatory Authority
IAM	Identity and Access Management
IDMP	Identification of Medicinal Products
IG	Implementation Guide
IT	Information Technology
ISO	International Organization for Standardization
MEB	Medicines Evaluation Board
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product (generally used in this document to describe products authorised via MRP/DCP/NP)
NCA	National Competent Authority
NOMA	Norwegian Medicines Agency
NP	National Procedure
NtA	Notice to Applicants
PMS	Product Management Services

PSMFL	Pharmacovigilance System Master File
QPPV	Qualified Person for PharmacoVigilance
RIMS	Regulatory Information Management System
SAFe	Scaled Agile Framework
SME Group	Subject Matter Experts Group
SE MPA	Swedish Medical Products Agency
SPOR	Management Services for Substances, Products, Organisations and Referentials
SRP	Subsequent Recognition Procedure
Q&A	Questions & Answers
UAT	User Acceptance Testing
UI	User Interface
UNICOM	Up-scaling the global univocal identification of medicines project
UPD	Union Product Database
VA	Variation Application
Vet	Veterinary
VMP	Veterinary Medicinal Products
VNees	Veterinary non-eCTD electronic submission.
XEVMPD	Extended EudraVigilance Medicinal Product Dictionary
XML	Extensible Markup Language