



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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PLM Portal eAF FHIR XML - Release Notes

EMA is pleased to announce the web-based Human Variations electronic application form (eAF) for Centrally Authorised Products (CAPs) has gone live on **4th November 2022**, on the new [Product Lifecycle Management \(PLM\) Portal](#). This is a big, first, milestone in the ongoing journey to improve the eAF and related processes. EMA has been collaborating with the UNICOM consortium to develop the human variation form and other new web-forms.

Following the release, users of the Human Variations eAF should expect continual work on improvements in the form of regular releases. These will be a mix of bug fixes, scheduled improvements, improvements based on user acceptance testing (UAT) feedback or that may be identified by users after the release and new features, such as additional structured data fields.

This document lists and briefly describes the new features and fixed issues included in the release of the PLM Portal **FHIR XML** only. For the Release notes related to the eAF, please visit the guidance on the [PLM Portal](#).

The most recent release appears first.

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About this Document

This document lists and briefly describes the new features and fixed issues included in the release of the PLM Portal **FHIR XML** only. For the Release notes related to the eAF, please visit the guidance on the [PLM Portal](#).

The most recent release appears first.

The components mentioned in this document are:

Component	Short Description
PLM Portal	This component relates to the website, the UI (user interface)
Human Variations eAF	The business process where MAH's create and edit their variation eAF (electronic application form) on the PLM Portal
PDF	The PDF that is available for download after the completion of an application
FHIR XML	The FHIR XML file attached to exported PDF

For additional information on the PLM portal:

- PLM Portal: [PLM Portal](#)
- If you encounter any issue that is not addressed by the above, visit the [EMA Service Desk portal](#)
- For more general information, visit: [PLM Portal eAF](#)

Version: 2.1.1 (Release date: 09/12/2024)

Version Content

The version 2.1.1 introduces several changes from the previously published package. The differences are detailed below:

Variation changes (FHIR 5.0.0 column):

- New note field for the Declaration of the applicant (line 183 in the "PLM Portal eAF FHIR Package (Mapping) 2.1.0", "Variation" tab)
- The cardinality of the unstructured changes was upgraded from 1 to N (line 72 and 73 in the "PLM Portal eAF FHIR Package (Mapping) 2.1.0", "Variation" tab)

Version: 2.1.0 (Release date: 28/10/2024)

Version Content

The version 2.0.1 was updated to 2.1.0 on the 28th of October because the underlying .NET version was upgraded from .NET6 to .NET8.

The previously published package remains valid.

Version Content

The version 2.0.1 introduces several changes from the previously published package. The differences are detailed below:

Medicinal Product changes (FHIR 5.0.0 column):

- MP9-MPD20 (see example in MedicinalProductDefinitionWithAllFieldsForPermissiveTestingV5.xml) – Legal Status Of Supply new mappings
- PPD10 (see example in PackagedProductDefinitionWithAllFieldsForPermissiveTestingV5.xml) - include the extension's url (codedUnit) and fix domain resource example
- PPD13-PPD23 (see example in PackagedProductDefinitionWithAllFieldsForPermissiveTestingV5.xml) – Legal Status Of Supply new mappings
- PPD29 – The PackagedProductDefinition.description field is now optional (it was mandatory)
- CUD1, CUD2, CUD3 & CUD4 (see ClinicalUseDefinitionWithAllFieldsForPermissiveTestingV5.xml)

Variation changes (FHIR 5.0.0 column):

- RA1: the applicationIdentifierNumber in the marketing regulated authorization is now labelled mrpVariationNumber
- RA7 (see RegulatedAuthorizationWithAllFieldsForPermissiveTestingV5.xml) – This reverts it to 'http://ema.europa.eu/fhir/extension/overviewTable' instead of just 'overviewTable'
- RA8 (every RegulatedAuthorization example and Full App) – the list ID 100000160962 (mistake) was replaced by the 100000000002 one

Improvements in the examples:

Full App Example:

- Mandatory strength was added to every Ingredient
- A packaging and a containedItemQuantity were added to every PackagedProductDefinition
- All countries are now presented with their short name: Portugal instead of Portuguese Republic. It was changed, where needed, in RegulatedAuthorization.region.coding.display

Ingredient Examples:

- the denominator's list was incorrectly 100000110633. It was updated to 200000000014.

Version: 2.0.0 (Announcement date: 31/01/2024 – Release date: 14/04/2024)

Version Goal

We are eager to announce the upgrade of the eAF human variation FHIR XML version 2.0.0 that includes the latest official FHIR version “Release #5 (5.0.0): <http://hl7.org/fhir/>”. This replaces the current version FHIR Release #5: Draft Ballot (4.6.0): <http://hl7.org/fhir/2021May/>, which will remain online for approximately 3 months to give consuming systems time to adapt to the change.

Version Content

The upgrade of the eAF XML to the current official Release #5 of FHIR is the first part of EMAs strategy to synchronize different projects on a stable FHIR version that will provide the necessary stability in the network to implement the new data exchange format on a larger scale.

Together with the upgrade to Release #5, we have reviewed and improved the eAF mappings in FHIR in order to provide the most stable version yet for consuming systems to start importing the eAF.

What this is not

This release note will enable consuming systems to read the message and extract the necessary data. **It is not a documentation to create the message itself.** The necessary Guide to create an eAF FHIR message is being worked on and will be published at a later stage.

How to read the release documentation?

To provide consumers of the FHIR XML message the easiest possible way to upgrade to the eAF XML 2.0.0.0 containing the new FHIR #5 resources or to start your implementation with the latest version, we have prepared:

1. **A change log: 2024 01 30 Changelog eAF Variation FHIR 4.6 to 5.0.xlsx**
This contains an extensive list of all changes done in the new eAF XML version with links to the data requirements, 4.6 Paths, 5.0 Paths and the reason for change
2. **A snapshot of the current eAF data requirements: 2024 01 30 AF Data Requirements.xlsx**
This contains all fields for variation and medicinal product being used now or in future versions of the PLM portal
3. **All resources in v4.6 and v5.0 as XML for an easy comparison usable for permissive testing: MedicinalProduct Domain Resources - 4.6 and 5.0, Variation Domain Resources - 4.6 and 5.0**
A complete list of examples for every resource in both versions to easily compare the changes and understand how the new structure looks like
4. **As complete as possible examples of an invented variation message exported in 4.6 and 5.0 from the PLM portal: eAF human variation 4.6.0 - 1.2.0.8.xml, eAF human variation 5.0.0 - 2.0.0.0.xml**
An example was created of a complete bundle that was filled in with a focus on completeness rather than realistic data. This is to be used to understand how the different resources behave in the bundle.

Version: 1.2.0 (Release date 21/11/2023)

Version Goal: Implementation of FHIR XML

Date: 21/11/2023

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Description
Implementation of the FHIR XML	FHIR XML 1.2.0	Commercially Confidential Data not related to the application content/variation removed from the FHIR XML

Issues fixed in this version

ID	Description	Comments
38300, 15895, 46485	Identify minimum set of fields required to export and update FHIR generation to exclude information not needed	<p>Removing Product data that has not been changed in the FHIR XML</p> <ol style="list-style-type: none">1. Only Resources that are needed for the PDF are also contained in the XML.2. Confidential data is not included when not needed. <p>Paradigm</p> <p>Rule Nr.1: If a resource has a change to 1 property the entire resource needs to be there.</p> <p>Rule Nr.2: If a resource has a link to a resource that is not being changed, the link should stay, but the resource that is being linked should not be there. This is to be able to compare resources and confirm that something/nothing has changed.</p> <p>Rule Nr.3: Resources pointed at by the Task should always be mandatory.</p> <p>Mandatory resources (always included, irrespective if they are being changed):</p> <ul style="list-style-type: none">• Medicinal ProductDefinition• IngredientDefinition<ul style="list-style-type: none">○ Reason: Substance Name○ <i>implicit: Link to medicinal product (extension) - not Admin product link</i>○ Role = Active• RegulatedAuthorization - for selected packages and med products (Type=Marketing Authorization)• PackagedProductDefinition - ONLY IF SELECTED• All Orphan Resources

		<ul style="list-style-type: none"> • Orphan RAs, GMP RAs, Paediatric RAs, Market Exclusivity and Market Protection RAs • Organization (type=MA Holder and Regulator - linked to the RegulatedAuthorization) • All parallel resources (MedicinalProductDefinition + RA) • Substances (role = active) • PaymentNotices • PractitionerRole and its organizations <p>Subtasks/Scopes, which are represented as FHIR Tasks, will no longer be contained resources, but flattened *</p> <p>Previous implementation: "/f:Bundle/f:entry/f:resource/f:Task/f:contained/f:Task" Adjustment: "/f:Bundle/f:entry/f:resource/f:Task"</p> <p>Suggestion for consuming systems using XPATH //Task[id/@value=substring-after(\$reference,'#')]//Task[id/@value=substring-after(\$reference,'Task/')]</p> <p>* See detailed picture below</p>
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Old paradigm(Task represented in orange and Scope represented in Yellow):


```

▼<Bundle xmlns="http://hl7.org/fhir">
  <id value="b7108cc5-360f-42cd-82ca-f568066bbd84"/>
  ▼<meta>
    <source value="http://ema.europa.eu/fhir/system/dadi/webform/1.110"/>
    <profile value="http://hl7.org/fhir/4.6.0/StructureDefinition/Bundle"/>
    <profile value="http://ema.europa.eu/fhir/definition/dadi/Bundle-variation/1.2.0.0"/>
  </meta>
  <type value="collection"/>
  ▼<entry>
    <fullUrl value="urn:uuid:ac0e9e5e-5e09-408b-8c62-51326d3ccad1"/>
    ▼<resource>
      ▼<Task>
        <id value="4688df5abd9d24edf8d69a30ce653a8a"/>
        ▼<contained>
          ▼<List>
            <id value="taskProductList"/>
            <status value="current"/>
            <mode value="working"/>
            ▼<entry>
              ▼<item>
                <reference value="MedicinalProductDefinition/600000001209"/>
              </item>
            </entry>
          </List>
        </contained>
        ▼<contained>
          ▼<Task>
            <id value="variation-3b6b96d93a21f59ff8d69a30ce653a8a"/>
            ▼<identifier>
              <system value="http://ema.europa.eu/fhir/scopeIdentifier"/>
              <value value="A.2.b) - Variation Type IB - 1"/>
            </identifier>
            ▼<partOf>

```

New Paradigm(Task represented in orange and Scope represented in Yellow):

```

▼<entry>
  <fullUrl value="urn:uuid:02bb49f7-2d01-4012-9003-53ee4b454060"/>
  ▼<resource>
    ▼<Task>
      <id value="4688df5abd9d24edf8d69a30ce653a8a"/>
      ▼<contained>
        ▼<List>
          <id value="taskProductList"/>
          <status value="current"/>
          <mode value="working"/>
          ▼<entry>
            ▼<item>
              <reference value="MedicinalProductDefinition/600000001209"/>
            </item>
          </entry>
        </List>
      </contained>
      <status value="requested"/>
      <intent value="order"/>

```

```

▼<entry>
  <fullUrl value="urn:uuid:49445506-ca20-47b3-a5c3-8bcfed65fd59"/>
  ▼<resource>
    ▼<Task>
      <id value="variation-3b6b96d93a21f59ff8d69a30ce653a8a"/>
      ▼<identifier>
        <system value="http://ema.europa.eu/fhir/scopeIdentifier"/>
        <value value="A.2.b) - Variation Type IB - 1"/>
      </identifier>
      ▼<partOf>
        <reference value="#"/>
      </partOf>
      <status value="requested"/>
      <intent value="order"/>
      ▼<code>
        ▼<coding>
          ▼<extension url="http://ema.europa.eu/fhir/extension/codeSystemName">
            <valueString value="Variation Classification"/>
          </extension>
          <system value="https://spor.ema.europa.eu/v1/lists/100000152091"/>
          <code value="100000152173"/>
          <display value="A.2.b - ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products"/>
        </coding>
        <text value="A.2.b"/>
      </code>
    </input>
  </resource>
</entry>

```

Known Issues

ID	Component	Short description
n/a	n/a	n/a

Version: 1.1.2 (Release date 10/02/2023)

Version Goal: Implementation of FHIR XML

Date: 10/02/2023

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the FHIR XML	FHIR XML 1.1.2	

Issues fixed in this version

ID	Description	Comments
36110	ASMF, DUNS Nr, Telephone and Email changes	Change ASMF, DUNS Nr, Telephone and Email mapping in FHIR according to the changes in the eAF
24565	Free text field changes	Limit width of free text fields
30382/30383/30387	Various refactoring	Ingredient/Ingredient Strength/Ingredient Documentation FHIR refactoring
38537	Device Definition	Attach every DeviceDefinition to a Medicinal Product
38779	ATC Source ID	Add the Source ID to the ATC while keeping the ATC name as well
37124/38274	Device variation	Minor fixes to the Device variation as new edge-cases were tested

Known Issues

ID	Component	Short description
38300	FHIR XML	Commercially Confidential Data not related to the application content/variation present in the FHIR XML

Version: 1.0.2 (Release date 16/11/2022)

Version Goal: Implementation of FHIR XML

Date: 16/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the FHIR XML	FHIR XML 1.0.2	This release note is for the BUGFIX version 1.0.2 release go-live 16/11/2022

Issues fixed in this version

ID	Description	Comments
26295 – FHIR XML	The HTML Change Provenance (unstructured provenance) doesn't contain the HTML changes when the proposed value and the present value are the same	This issue resulted a missing present and proposed section in the FHIR XML and in the pdf export when same value was presented in both 'present' and 'proposed' fields e.g., if user had added 'see details on separate annex' in both fields, the present and proposed sections were not available in the XML and were hidden in the pdf.
26247 – FHIR XML	Impossible to use the same image twice in the text areas in a form	

Known Issues

ID	Component	Short description
Known limitation	FHIR XML	Commercially Confidential Data not related to the application content/variation present in the FHIR XML

Version: 1.0.0 (Release date 04/11/2022)

Version Goal: Go-Live PLM Portal

Date: 04/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the FHIR XML	FHIR XML 1.0.0	This implementation is the first version of the FHIR XML export

Known Issues

ID	Component	Short description
Known limitation	FHIR XML	Commercially Confidential Data not related to the application content/variation present in the FHIR XML