



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

EMA Write PMS API implementation Guide

Version 1.1

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Glossary

API: Application Programming Interface

EMA: European Medicines Agency

FHIR: Fast Healthcare Interoperability Resources

HTML: HyperText Markup Language

IG: Implementation Guide

JSON: JavaScript Object Notation

PMS: Product Management Service

ZIP: Compressed (zipped) folder

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Summary of changes

Version 1.1 of the EMA Write PMS API Implementation Guide outlines the behaviour of the PMS Write API in version 1.1.0.0. **This version will be deployed to UAT on 18 July 2025 at 6:00 PM CEST.** From that point onward, the version numbers of the Implementation Guide and the PMS Write API will be aligned for the first three digits. The fourth digit will be reserved for bug fixes that do not require changes to the Implementation Guide.

Below is a table and accompanying descriptions outlining the main changes introduced in version 1.1.0.0:

PMS Write API - FHIR 5.0.0 - IG 1.1.0 - Main changes			
Chapter 2 code	Name	Previous mapping	New Mapping
2.X (to be created)	Authorization Type	RegulatedAuthorization.type.coding.code=2200000000099	RegulatedAuthorization.type.coding.code=200000051585
5.9.6	Data Carrier Identifier	PackagedProductDefinition.packaging.identifier	PackagedProductDefinition.identifier

IG changes:

- Mapping table also updated to correct https systems to http and to add new PMS section references (to match the Chapter 2 document)

API changes:

- A few non-editable ActivityDefinition and RegulatedAuthorization fields were editable by mistake
- Logging improved, to have a better picture of the interactions with the API in real time
- Warning in case we attempt to merge a product without package sizes

Profile changes

- The submission Bundle type was changed from 'collection' to 'transaction'
- A few nodes changed from mandatory to optional (or the opposite) – this did not affect any editable node
- Corrected some value set issues

1. Scope of this guidance

The “EMA Write PMS API implementation Guide for the PMS Enrichment process” can be found in the ZIP file available on the [EMA PMS Webpage](#).

This FHIR Implementation Guide (IG) ZIP package is a comprehensive resource for developers, implementers, and stakeholders who are working to adopt and implement healthcare standards based on FHIR (Fast Healthcare Interoperability Resources).

The package acts as an all-in-one toolkit to ensure that healthcare data can be exchanged efficiently, accurately, and securely, in full compliance with FHIR standards.

To access the guide, the following steps should be followed:

1. Unzip the file available on the [EMA PMS Webpage](#).
2. Open the index.html file within the folder.
3. Read the home page for a general overview and starting point.
4. Click on the 'Artifacts Summary' to view the profile definitions.

2. Contents of the IG

2.1. FHIR Profiles and Extensions

- **Profiles:** Customized constraints on FHIR resources to meet specific requirements (e.g., specific formats for MedicinalProductDefinition, PackagedProductDefinition, ActivityDefinition or RegulatedAuthorization).
- **Extensions:** Additional data fields not available in the standard FHIR resources, enabling greater flexibility.

2.2. Value Sets and Code Systems

- **Value Sets:** Lists of standardized codes or terms used to populate resource fields (e.g., marketing statuses or product categories).
- **Code Systems:** Definitions of coding systems referenced by value sets.

2.3. Conformance Resources

- **Implementation Examples:** Guides for specific systems or scenarios.

2.4. Technical Artifacts

- **StructureDefinitions:** Specifications for resources, profiles, or extensions.
- **XML and JSON Representations:** Files for direct implementation or validation.