



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

EMA Write PMS API implementation Guide

Version 1.2.0

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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

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Summary of changes

Version 1.2.0 of the EMA Write PMS API Implementation Guide outlines the behaviour of the PMS Write API. This IG describes how the PMS Write API will behave in v1.2.0.0. The current one is v1.1.0.2. **This version has been deployed to UAT on 7 August 2025 at 6:00 PM CEST.**

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

PMS Write API - FHIR 5.0.0 - IG 1.2.0 - Changes			
Change Type	Change Name	V1.1.0	V1.2.0
FHIR Mapping	New Data Carrier Identifier mapping (field 5.9.6 in Chapter 2)	<pre><identifier> <system value="http://ema.europa.eu/fhir/dataCarrierIdentifier" /> <value value="12345678901234" /> </identifier></pre>	<pre><identifier> <system value=http://spor.ema.europa.eu/v1/lists/1000000000009/terms/100000167575 /> <value value="12345678901234" /> </identifier></pre> The system term can assume one of the following codes: 100000167575 (GS1 Global Trade Item Number) 200000027029 (Pharmacy Product Number) 200000027030 (National Trade Item)
Validation	Profile Validation Enabled	Not enforced – The IG acted as a baseline, but its underlying profiles weren't used to validate the incoming FHIR message	Enforced – The IG is not only a baseline but its profiles are used to validate the incoming FHIR Message
Automated testing	New Unit Tests	50 unit tests	69 unit tests
Automated testing	New Integration Tests	3 integration tests	4 integration tests

Auditing	New structured logging for error messages	Structured logging for all successful requests and unstructured logging for error messages	Structured logging for both successful and erroneous requests
Error messages	More detailed error messages	Relatively low number of error messages, none of them listed in the IG	New error messages added (all listed in the IG's homepage, chapter 1.7)
Operational	Internal health checks to ensure connectivity across modules	End-to-end testing of the entire workflow High overhead, slower to execute Reactive	Lightweight, dedicated health check internal endpoint Minimal overhead, fast response Proactive

1. Scope of this guidance

The "EMA Write PMS API implementation Guide for the PMS Enrichment process" can be found in the following link:

- <https://pms.ema.europa.eu/fhir/ig/>

This FHIR Implementation Guide (IG) 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. Open the link mentioned above
2. Read the home page for a general overview and starting point.
3. Click on the 'Artifacts Summary' to view the profile definitions.

2. Contents of the IG

2.1. FHIR Profiles and Extensions

- **Profiles:** Customised 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.