



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2020
EMA/676108/2019
Information Management

Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Chapter 6: Technical specifications

Version 1

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

An agency of the European Union



Table of contents

Technical specifications	3
1.1. Introduction	3
1.2. Main API concepts	3
1.3. API specification	3
1.4. FHIR profiles.....	4

Technical specifications

1.1. Introduction

The technical mechanism for product information management is a RESTful Application Programming Interface, known as the SPOR API. The SPOR API offers services to work with elements in all four domains (Substances, Products, Organisations and Referentials). Support for Products and Substances has been introduced in version 2 of the SPOR API, whereas support for Organisations and Referentials is already a publicly service available since 2017.

1.2. Main API concepts

The SPOR API v2 has been built by using HL7 FHIR R3 as an overarching standard. At the same time, it tries to follow the same principles as the existing SPOR API v1 and leverages both existing FHIR and SPOR API v1 resources and endpoints where applicable.

The SPOR API v2 is formally presented through an API specification, which is meant to enable developers to build an integration with SPOR services within their own local systems and fulfil their own business and regulatory requirements. The specification is the main reference point and in order to understand how to implement client systems, the following key elements should be considered:

- **Resources:** this refers to the formal representation of a set of data structures that can be exchanged between the client and the SPOR API in any specific communication. The resources are publicly available in the HL7 FHIR server. For simplicity, all relevant resources are also linked from the SPOR API specification document.
- **Services:** this refers to the formal representation of the actions that can be executed against the existing Resources. The combination of Services and Resources gives developers the capability to understand the features that the SPOR API offers.
- **Common mechanisms:** since the API is based on FHIR and RESTful principles, the specification provides overall information regarding how these common mechanisms work. This includes, amongst others: usage of HTTP methods and codes, usage of FHIR bundles, FHIR extensions, etc. Importantly, it also describes the versioning mechanisms that guarantee backwards compatibility within a structured governed process.

1.3. API specification

The API specification is mainly composed of:

- a document that details all the concepts described above;
- a list of resources available live in the HL7 FHIR server.

More tools shall be provided to developers in future stages and as the regulatory and technical requirements evolve.

The recommended approach to the above is to read the specification document first. The links to relevant resources are part of the API specification document, whilst better understanding is obtained if resources and services are reviewed in conjunction. The specification document is the mechanism to glue these concepts together.

The SPOR API v2 specification is provided separately from this document and it is accessible through [this link](#).

1.4. FHIR profiles

The resources as defined in the current API specification offer coverage for the full IDMP model. The overall implementation of the ISO IDMP format and structure shall be done in phases. Therefore, relevant data elements and resources within the overall FHIR model will be enforced within each phase of the development of PMS. The mechanism to narrow the overall IDMP model down and to describe technically all the business rules to be enforced in the FHIR message is referred as to the *FHIR profiles*. More can be read about FHIR profiles within the API specification document.

In the present draft release of the Implementation Guide, no FHIR profile is provided. They are being built based on the business rules contained in this guide and they shall be provided at a later stage.