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European Medicines Agency

Call for user acceptance testers for the read functionality in the Public Product Management Service (PMS) Application Programming Interface (API)

Contents

Dear interested organisations,

Following development of the Public Product Management Service (PMS) Application Programming Interface (API), a User Acceptance Testing (UAT) phase is planned to be launched in Q1 2026.

UAT purpose

to verify that external users can successfully retrieve a limited set of product data from the Public PMS API through their machine-to-machine connection.

UAT timeframe and execution details

The UAT will be executed as follows:

- 1st UAT round:
  - Scope: test the Public PMS API read access and identify any bug (technical or security-related bugs) requiring fix activities by EMA to ensure the smooth and functional release in production environment. Test the access to a limited product dataset as per revised EU IG Annex A, Ch. 5.
  - Testers are expected:
    - Align their internal systems with the Public PMS API data model.
    - Verify successful access to the Public PMS API.
    - Confirm that access to the publicly accessible product dataset is successful.
    - Ensure that access to the confidential product dataset is restricted or blocked.
    - Confirm the search parameters are functional and work as per design.

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        - Confirm the public statement on the scope of use is visible.
        - Report any bugs or issues identified during User Acceptance Testing (UAT).

- 2nd UAT round:
    - scope: confirm whether the fixes implemented by EMA have addressed the previously identified issue(s) by the testers.
    - Testers are expected to:
        - re-test the bug(s) previously identified in PMS UAT environment
        - provide the feedback on whether the fix has resolved the issue or not.

Testers' selection criteria

We invite each interested organisation to submit their nomination based on the below criteria:

1. **Nomination Limit** – The Agency invites each stakeholder group to put forward their nominations. Please note that the Agency will ultimately select a maximum of ten (10) representatives from each stakeholder group to participate in the Public PMS API User Acceptance Testing (UAT). **Each single organisation can nominate one tester that will act as main contact point and one eventual back-up tester**. In case it is considered that the nomination of additional representatives is essentially required for compliance with criteria 2 (Diverse Software Representation), please submit a justified request for the nomination of those additional representatives. Note that it may not be technically feasible for EMA to accommodate such request. Nominations will be assessed and accepted on a first-come, first-served basis.
2. **Diverse Tester Representation** – To ensure broad, fair, and relevant coverage of testing scenarios for the Public PMS API, testing activities should involve a diverse set of organisations that represent key stakeholder groups in the medicinal product data and regulatory ecosystem:
    - **Public and international health organisations**: Multinational or national regulatory authorities, public health institutions, and intergovernmental organisations actively engaged in medicines regulation, pharmacovigilance, and health data management. These entities may use PMS data to support public health objectives, regulatory transparency, and the consistent management of medicinal product information across jurisdictions.
    - **Data and standards bodies**: Organisations responsible for developing, maintaining, or implementing health data standards and reference terminologies. Their participation may support validation of data structures, terminologies, and interoperability frameworks.
    - **Software and system developers**: Organisations and developers building or maintaining digital systems that consume or integrate medicinal product data in line with IDMP, PMS, or FHIR standards. This category includes:
        - Regulatory and compliance software providers
        - Healthcare IT vendors (e.g., prescribing, or dispensing systems)
        - Pharmacovigilance and safety data system developers
        - Integration service or middleware providers
        - Health data analytics companies

Their participation ensures that the PMS API is technically robust, interoperable, and usable across diverse healthcare and regulatory systems.

- **Patient, Healthcare Professional Groups and Academia**:
  - Patient organisations, patient advocacy groups, or health information portals that promote transparency, access to trustworthy medicinal product data, and digital literacy.
  - Healthcare professional organisations such as medical societies, pharmacy associations, or hospital networks interested in accurate, up-to-date product information.
  - Academic and research groups focused on health informatics, evidence-based prescribing, or pharmacovigilance education, or related fields.

  Their participation helps ensure that PMS public data is usable, understandable, and valuable for end users, supporting transparency, informed healthcare decisions, and digital health innovation.

Marketing Authorisation Holders (MAHs) and National Competent Authorities (NCAs) are also welcome to participate in the UAT, subject to seat availability.

3. **Essential Technical Expertise:**
   - Experience in **REST API development and integration**
   - Proficiency in **JSON/XML data handling and processing**
   - Knowledge of **FHIR standards** or a strong willingness to learn
   - Understanding and implementation of **API security best practices**

How to submit your application

Kindly forward the nominations (specifying the organisation name, and the email address for the candidate, including the tester (main contact point) and one eventual back-up person) to the PMS Change Management contact point, Scarpati Caterina caterina.scarpati@ext.ema.europa.eu mailto:(CC: PLM.ValueStream PLM.ValueStream@ema.europa.eu), by **EOB 12th January 2026**. The collection of the nominations is performed in line with the principles outlined in the PMS Data Protection Notice.

Please note that a dedicated kick-off meeting will be organised with the selected candidate testers shortly before the start of the UAT, which is expected to begin in February 2026. The event aims to provide insights on how to access the Public PMS API through a machine-to-machine connection to retrieve public data from the PMS. It will also clarify how the UAT will be organised and provide key information to testers, enabling them to effectively prepare for and execute the tests.

Functional and technical overview

The PMS Public API implements the FHIR R5 standard and supports use cases of searching for Medicinal Products by search parameters and retrieving the full public data set for specific Medicinal Product. This will be enabled through 2 API endpoints, one for searching and one for retrieving all information of a Medicinal Product based on its PMS ID. The core FHIR resource used by the API is MedicinalProductDefinition. Please see Chapter 2 of the PMS EU IG for details on the full use of FHIR in PMS and FHIR paths.

PMS structures data by making use of identifiers from the other SPOR data domains: Referentials, Organisations and Substances.

The technical specification is currently work in progress and will contain details on:

- API endpoints
- search parameter syntax
- pagination
- how references to other SPOR data should be interpreted

Supporting materials

- Substance and product data management services | European Medicines Agency (EMA)
- Revised Annex A to Ch 5 file listing publicly accessible data elements
- Public PMS API technical specifications