

Elektronizácia v EÚ

IRIS – iSPOC – PML – ePI

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Štátny ústav pre kontrolu liečiv

SARAP, 03.06.2025



IRIS

<https://iris.ema.europa.eu/>



❖ platforma na výmenu regulačných a vedeckých informácií s EMA

❖ centralizované lieky

❖ možnosti rôznych postupov (orphan dezinácia, pediatrické procedúry, SA, inšpekcie, marketing status, eAF, PMS a ePI)

12 March 2025 - EMA/444925/2018

IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants Version 3.7

Welcome to IRIS

A secure online platform for handling product-related scientific and regulatory procedures with EMA

Sign In



Quick links



Access & submission

Learn about the IRIS registration and submission process



Public registers & lists

Information on organisations, substances, orphan designations, parallel distribution notices, and veterinary signals



Guidance & support

Reference additional materials to assist you with working in IRIS



News

Stay up to date with latest information on IRIS and participate in the online Forums



Home > **IRIS Stakeholder Forums**



IRIS Stakeholder Forums

Welcome! **IRIS stakeholder forums** are a **public** platform where users (primarily applicants) can stay up-to-date on the latest IRIS news (e.g., new IRIS features, release information), ask each other questions, provide suggestions, and discuss best practices related to working in IRIS. While posts are visible to everyone, you need to be logged in to create a new thread or reply to an existing one.

EMA staff may intervene in the forums, but replies to individual questions cannot be guaranteed, as the forums do not replace the established EMA communication channels:

- [EMA ServiceNow](#) for access and registration requests and for reporting faults;
- [Ask EMA](#) for general questions not related to a specific submission/procedure;
- Direct replies to IRIS emails (without changing the subject), when responding to issues relating to a specific procedure.

Please note any text contained in the threads of these forums is **publicly available**, therefore please **do not post any type of confidential information**.

Forum	Last Post	Threads	Posts
What's New in IRIS New features in IRIS	 Caterina Scarpati 5 days ago	119	262
General Discussion and self-help Use this category for non-specific topics.	 Kamila Tomaszewska 4 days ago	227	624


i-SPOC Industry Single Point of Contact


- Kontakt slúžiaci na rýchlu komunikáciu medzi MAH a EMA ohľadne dostupnosti liekov (zoznam kritických liekov)
- Všetci MAHovia v EÚ sú povinní zaregistrovať kontaktné miesto

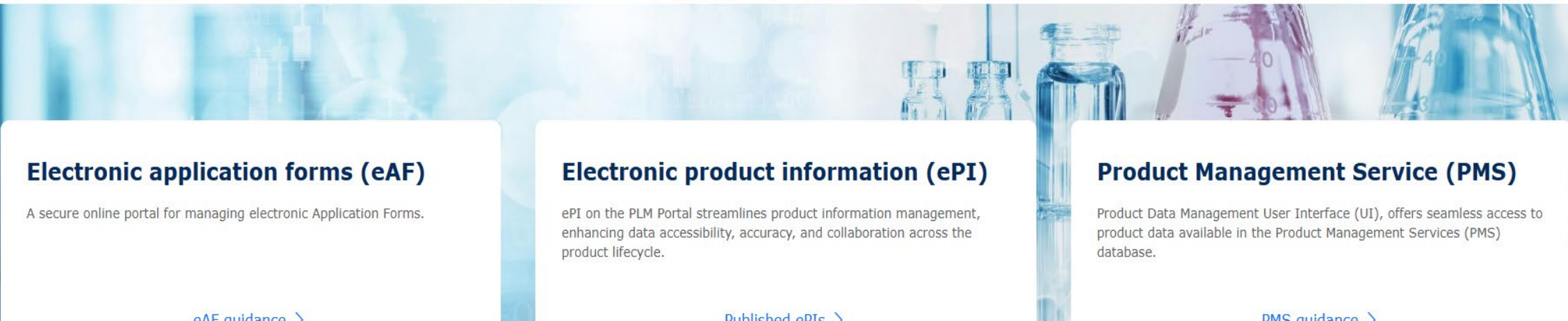


na online platforme **IRIS**
do 2. septembra 2022

PLM Product Lifecycle Management Portal

 Product Lifecycle Management Portal

SPOR  IAM IRIS Forum [Sign in](#)



Electronic application forms (eAF)

A secure online portal for managing electronic Application Forms.

[eAF guidance >](#)

Electronic product information (ePI)

ePI on the PLM Portal streamlines product information management, enhancing data accessibility, accuracy, and collaboration across the product lifecycle.

[Published ePIs >](#)

[ePI guidance >](#)

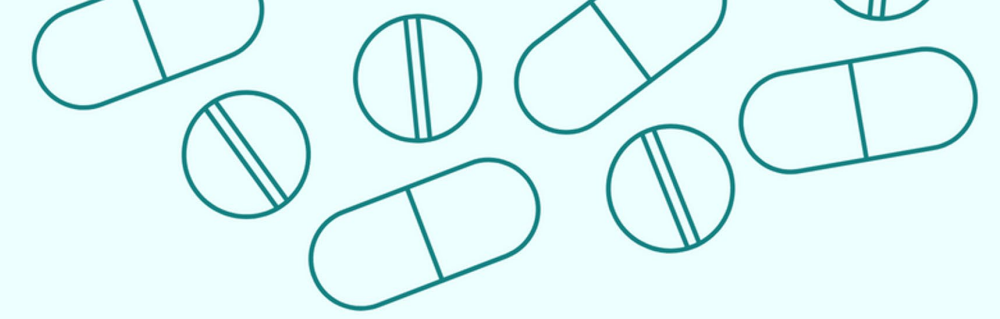
Product Management Service (PMS)

Product Data Management User Interface (UI), offers seamless access to product data available in the Product Management Services (PMS) database.

[PMS guidance >](#)

Quick links

eAF news	ePI news	PMS news
eAF release notes	ePI release notes	PMS release notes
eAF FHIR XML release notes		



eAF - zmenové žiadosti - vysoké odporúčanie!

[2025/05/21 - Recommended use of web-based Human variations electronic Application Forms \(eAFs\) for non-CAPs](#)

[2025/04/14 - Email authentication for EMA applications: Complete your account conversion by 8 May 2025](#)

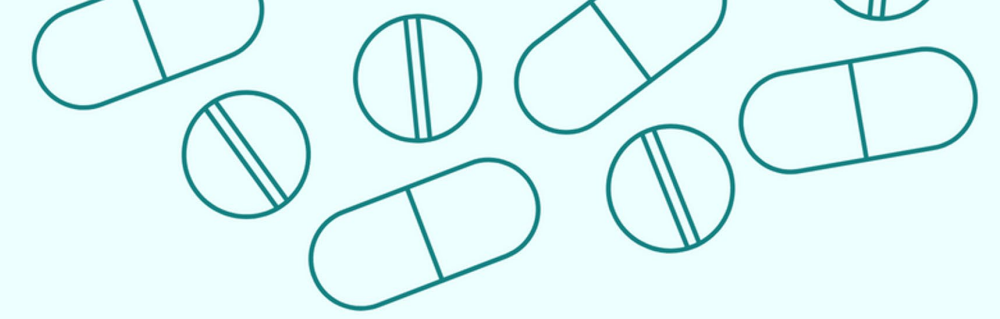
[2025/04/04 - Update on web-based Human variation electronic Application Forms \(eAFs\) timeline](#)

[2025/03/05 - PLM Portal eAF – Integrity stamp go-live on 6 March](#)

[2025/02/13 - Production go-live for submissions of human variations web-based eAFs for non-CAPs](#)

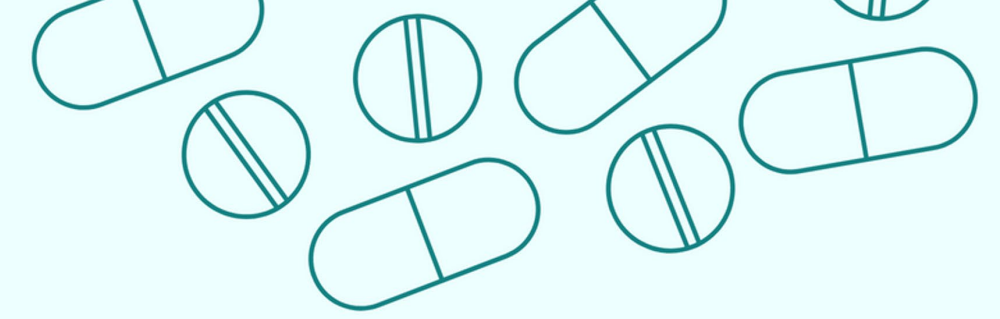
[2025/01/30 - Reminder: Email authentication to EMA systems - Timeline to convert your user](#)

[2025/01/27 - eAF updates and related training sessions happening in Quarter 1 2025](#)



PMS – Product Management Service

- Komplexné úložisko - databáza
 - Union list of critical medicines
 - Zosúlad'ovanie údajov z lokálnych národných databáz
- * art 57 database!!!

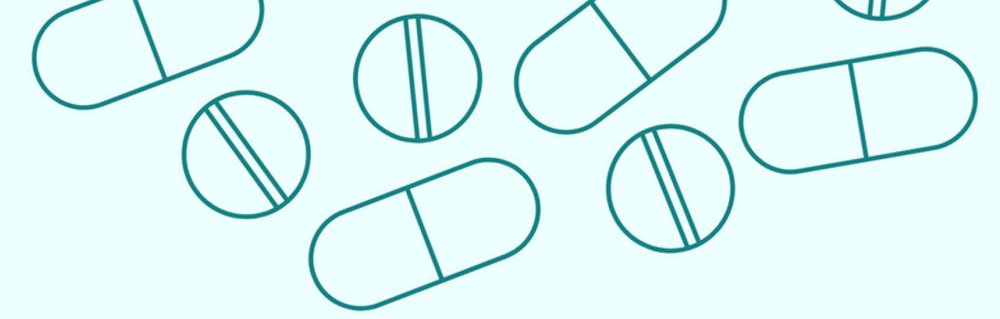


ePI – Electronic product information

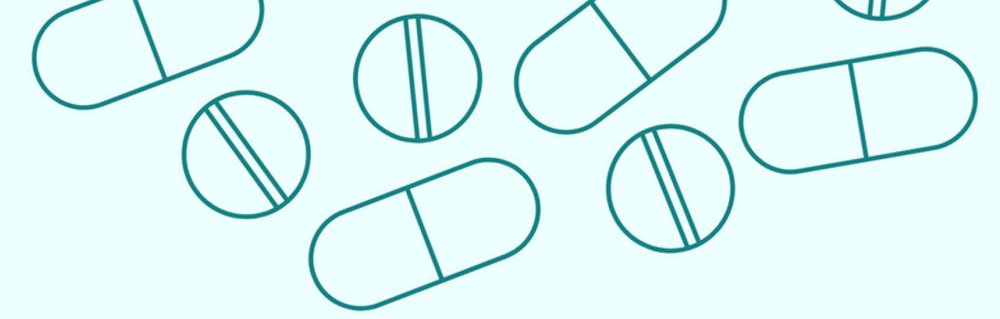
- lepšia dostupnosť aktuálnych informácií počas celého životného cyklu lieku
- Pilotný projekt – EMA, ES, DK, SE, NL

ePI - How to validate ePI against the EU ePI Common Standard Article describes how to validate FHIR files against the EU ePI Common Standard on a user's local machine
ePI - FHIR Implementation Guide for ePI Preview of the FHIR Implementation Guide for ePI to enable creation of ePI according to the EU ePI Common Standard
ePI - User Guide for Regulators Instructions for ePI Approvers and Publishers to navigate the tool and approve and publish ePI after they have been submitted by a pharmaceutical company
ePI - Known Issues Details of all known issues in the PLM portal – ePI that the ePI team is aware of and workarounds where available.
ePI - Frequently Asked Questions (FAQs) Document Frequently Asked Questions (FAQs) document on electronic Product Information
ePI - Procedural Guide Description of ePI processes within regulatory procedure timeframes for applicants participating in the ePI pilot.
ePI - User Guide for Applicants Instructions for ePI Applicant Managers and Contributors to navigate the authoring tool and create, prepare and submit ePI to regulators
ePI - Registration Guide

ePI



PMS





ePI vs ePIL

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Ďakujem za pozornosť

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