ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

Elektronizácia v EÚ

IRIS – iSPOC – PML - ePI

PharmDr. Ivana Pankuchová

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 dezignácia, 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

EUROPEAN MEDICINES AGENCY
IRIS

Home | Forums | Products | PLM | Sign in

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

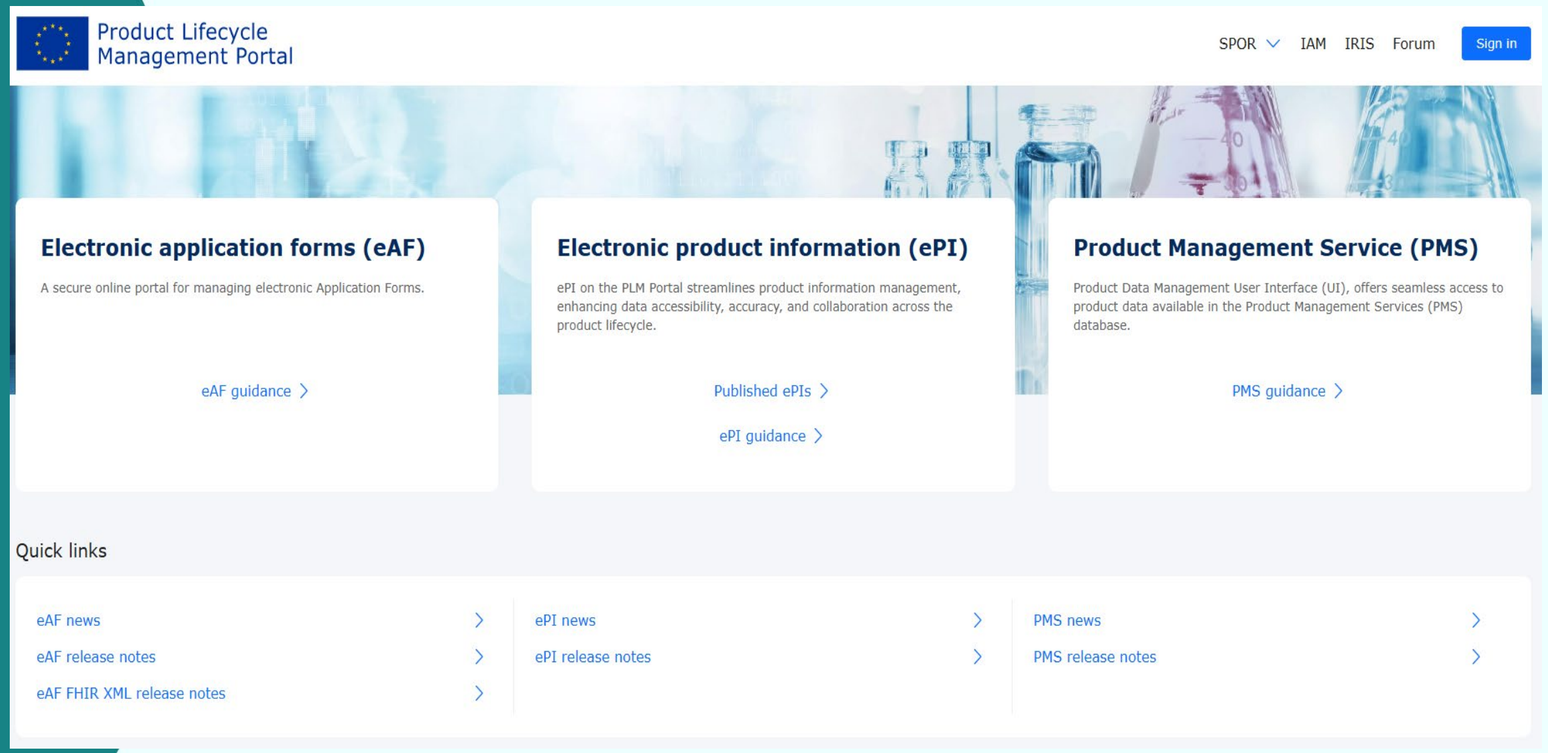
- Kontakt slúžiaci na rýchlu komunikáciu medzi MAH a EMA ohľadne dostupnosti liekov (zoznam kritických liekov)

- Všetci MAHovia v EÚ sú povinní zaregistrovať kontaktné miesto

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

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

PLM
Product Lifecycle Management Portal



SÚKL
STÁTNY ÚSTAV PRE KONTROLU LIEČIV

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

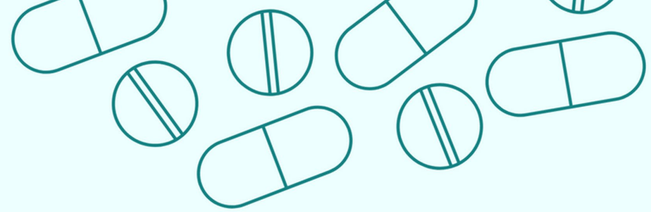
2025/03/05 - PLM Portal eAF – Integrity stamp go-live on 6 March

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

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV



PMS – Product Management Service

- Komplexné úložisko - databáza

- Union list of critical medicines

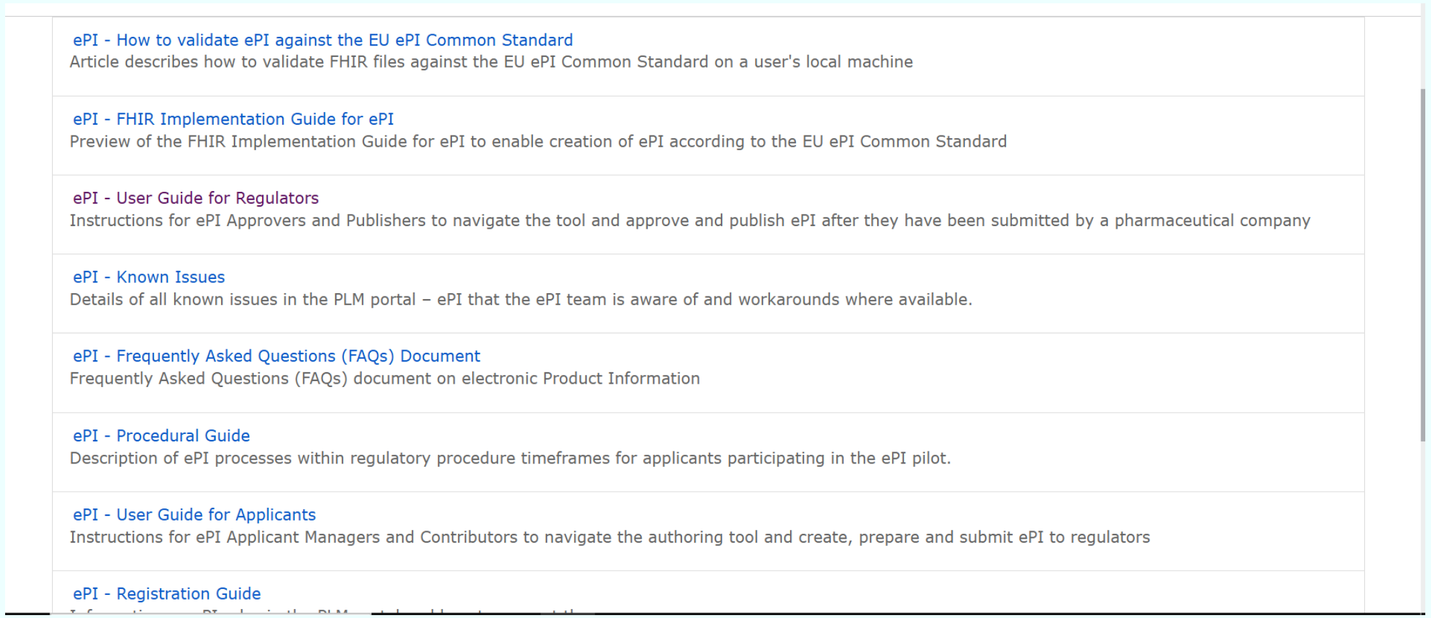
- Zosúlaďovanie údajov z lokálnych národných databáz

* art 57 database!!!

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

ePI – Electronic product information

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



SÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

ePI

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

PMS

ePI vs ePIL

?

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV

Ďakujem za pozornosť

PharmDr. Ivana Pankuchová

ŠÚKL
ŠTÁTNY ÚSTAV PRE KONTROLU LIEČIV
1964 2024 60 ROKOV REGULÁCIE LIEČIV