



AEMPS – Review  
of ePI from a  
regulator  
perspective

Presented by: Evin Drusys  
AEMPS IT Division

# ePI Definition

**ePI** is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.



**EU ePI common standard** based on FHIR to support a harmonised ePI across the EU network



**Fast**  
**Healthcare**  
**Interoperability**  
**Resources**

Adopted EU Common Standard for ePI published on GitHub:  
<https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard>

# ePI Minimum Viable Product

## ePI authoring portal

enables ePI creation, preview, update, upload (in FHIR) and download (in FHIR, Word)



User: Companies

## Rich text editing functionality

supports creation and editing of ePI with all styling aspects needed for PI documents



User: Companies

## Repository and API

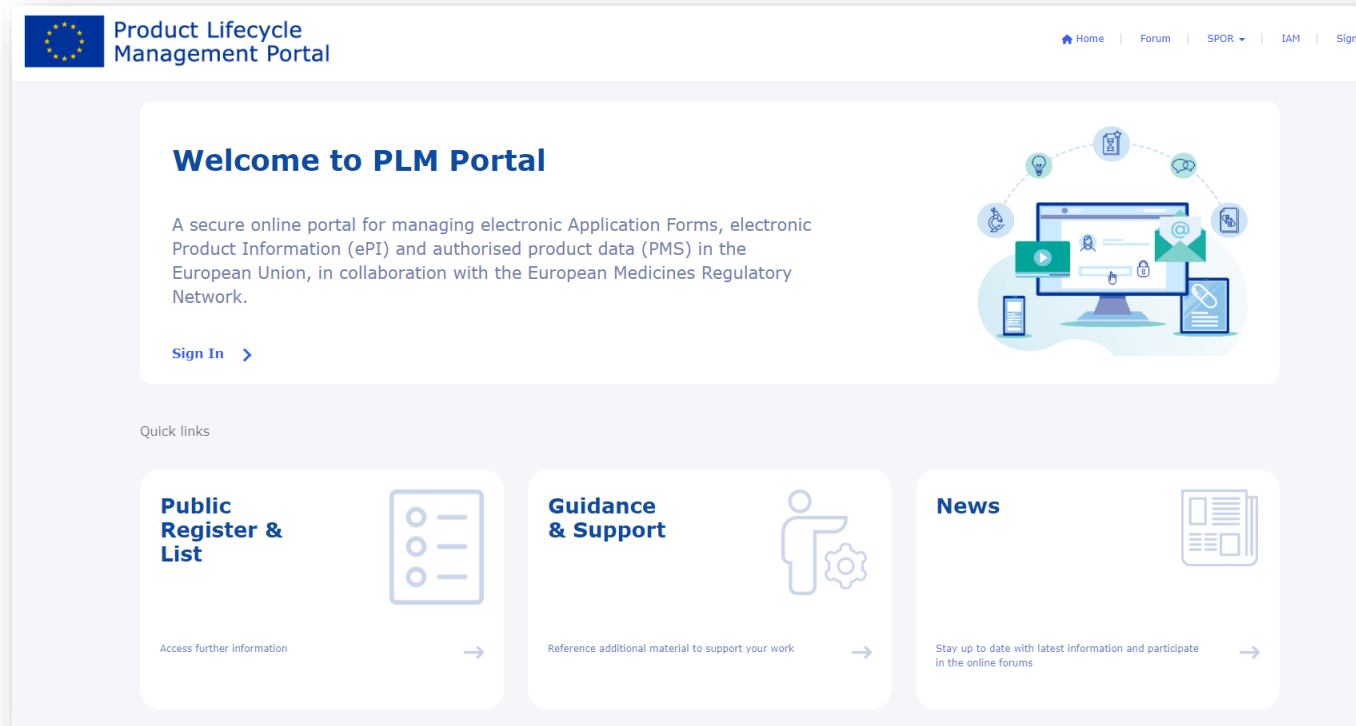
ePI to be stored in FHIR server and made available to websites and machines via the ePI API



Users:  
Companies  
Regulators  
eHealth developers

# ePI MVP in PLM portal

<https://plm-portal.ema.europa.eu/>



From the same portal, applicants can manage ePI, electronic application forms and product data.

# ePI editor for authoring PI documents

Home > ePI Portal - New ePI

EPI/23/73 / Draft  
Pre authorisation (ePI for new medicine) / Human / CAP  
Name of medicinal product - *Demo medicine* Procedure Number - *EMEA/H/C/01234*

SmPC ANNEX II Label PL

Human-CAP Template SMPC (EN)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

4.2. Posology and method of administration

Posology

Paediatric population

Method of administration

4.3. Contraindications

4.4. Special warnings and precautions for use

4.5. Interaction with other medicinal products and other forms of interaction

4.6. Fertility, pregnancy and lactation

## Demo medicine

NAME OF THE MEDICINAL PRODUCT

File Edit View Insert Format Tools Table Help

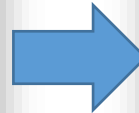
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# Reviewing ePIs

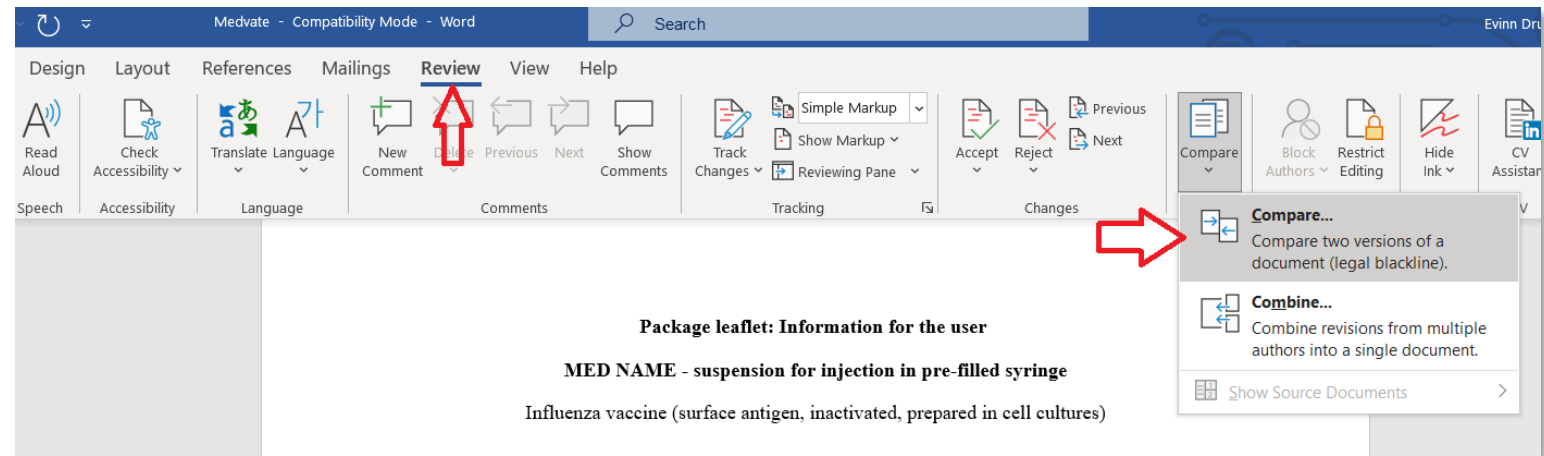
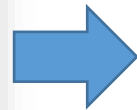
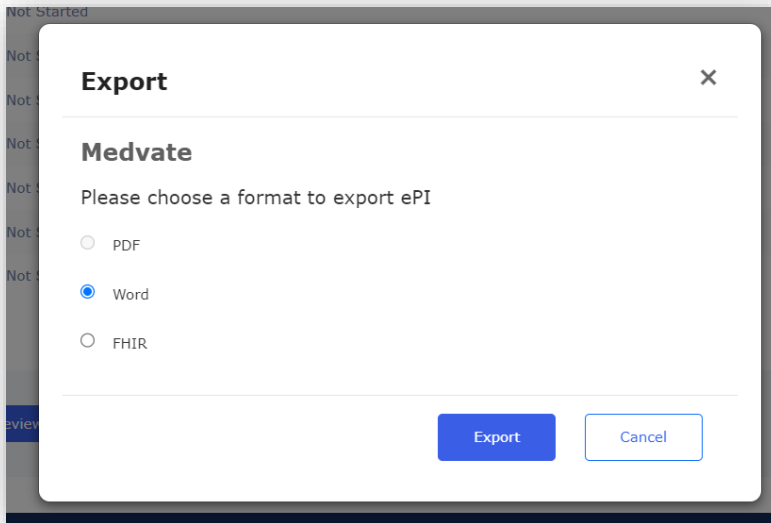
There are two convenient ways that regulators can review the submitted ePI

## 1. Via preview in ePI portal



# Reviewing ePIs

2. Exporting to Word from the ePI portal and using the Review → Compare feature in Word



# Regulator view

Home > ePI List

Draft Complete Pre Opinion **Complete Post Opinion** Published Deactivated All

Column visibility Refresh Download

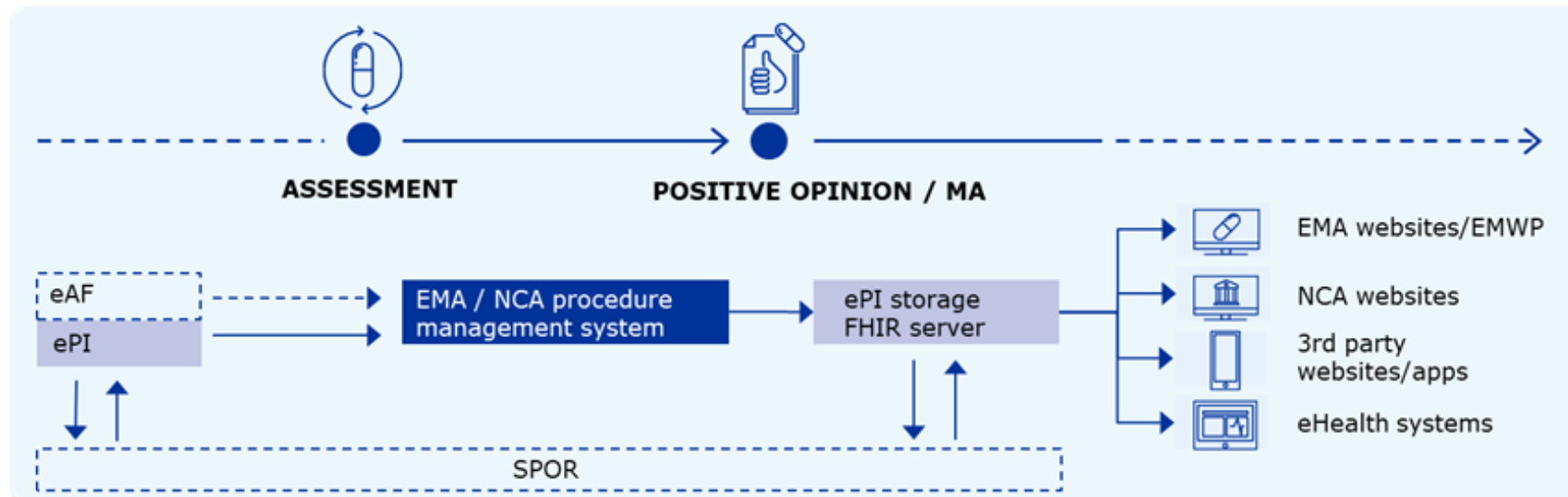
Search

EPI ID	Name of medicinal product	Procedure no.	Authorisation type	Reference MAH	Approved by	Approved on	Published by	Published on	Status	Action
Manage ePI	Test		CAP	test org	AV	19/01/2023 12:07 PM			Complete Post-opinion	⌵
Manage ePI	TestDevmed	1234	CAP	test org	Test	23/01/2023 11:12 AM			Complete Post-opinion	⌵
EPI/23/54	QRD template		CAP	UAT ORG					Complete Post-opinion	⌵
EPI/23/41	Test.	copy	CAP	European Medicines Agency					Com	<ul style="list-style-type: none"> <li>View/Manage ePI</li> <li>Deactivate ePI</li> <li>Approve for publication</li> </ul>



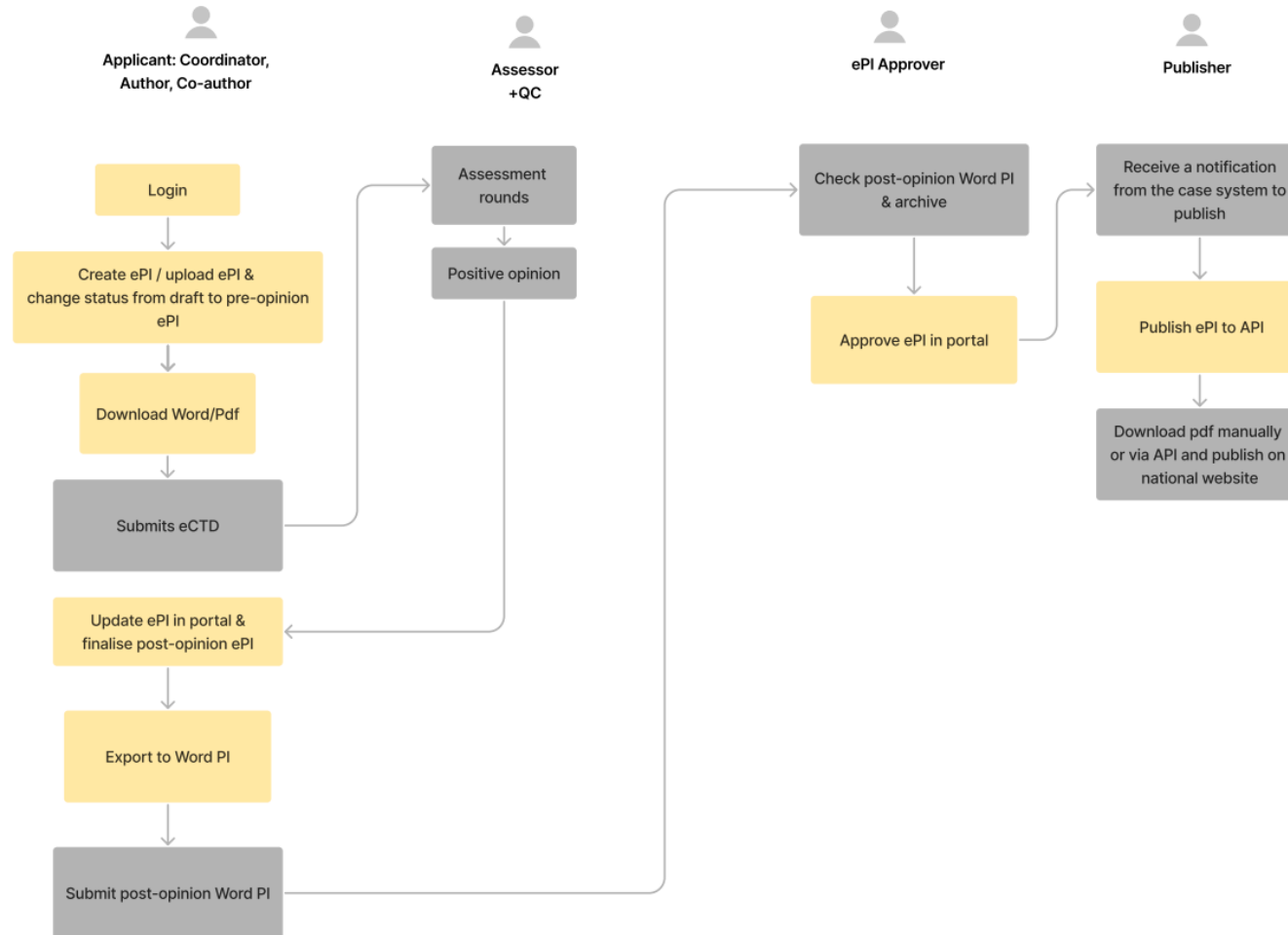
# EPI Pilot Minimum Viable Product (MVP)

- MVP will be piloted for CAPs(EMA) and NAPs (Denmark, Netherlands, Spain, Sweden).
- Small number of real-time procedures.
- Beginning H2, 2023 & first outcome report Q1, 2024.
- Portal user guide & procedural guidance in preparation.
- The MVP enables an early version of ePI with limited features that can be used by early adopters. The MVP is a ready-to-use, first release of a product to be used in the business process, and not a prototype.
- The MVP enables creation of ePI at point of application and update following positive opinion.



# Example regulatory procedure

## Pure NAP - initial



# ePI System Demos

- Most recent [demo 22<sup>nd</sup> of March](#)
- Recording available on EMA website/YouTube
- No invitation needed: join livestream on YouTube
- Next demo June 2023

## Quarterly system demo - Q3 2022 ← Share

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📅 **Date:** 28/09/2022

📍 **Location:** Online, 09:00 - 12:30 Amsterdam time (CEST)

### Event summary

This is the third system demo of 2022, the fourth ever held by EMA as part of its [Agile transformation](#).

A system demo is an event held at the end of a programme increment (a three-month period of work) to demonstrate the developments achieved in that period and collect stakeholder feedback.

Participants have the opportunity to review what has been delivered, comment and ask questions on future product increments (planned chunks of work on the final system).

EMA will demonstrate developments with its [DADI project](#), [Product Management Service](#), [Electronic Product Information \(ePI\)](#), [Emergency Task Force Support](#), [Veterinary Signal Management](#), [Inspections](#), [Parallel distribution](#) and [Medicines Shortages](#).

The event is broadcast live.

A video recording will be made available after the event.

# Thank you for your time

If you have any questions please contact: [efoster\\_externo@aemps.es](mailto:efoster_externo@aemps.es)