AEMPS – Review of ePI from a regulator perspective

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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

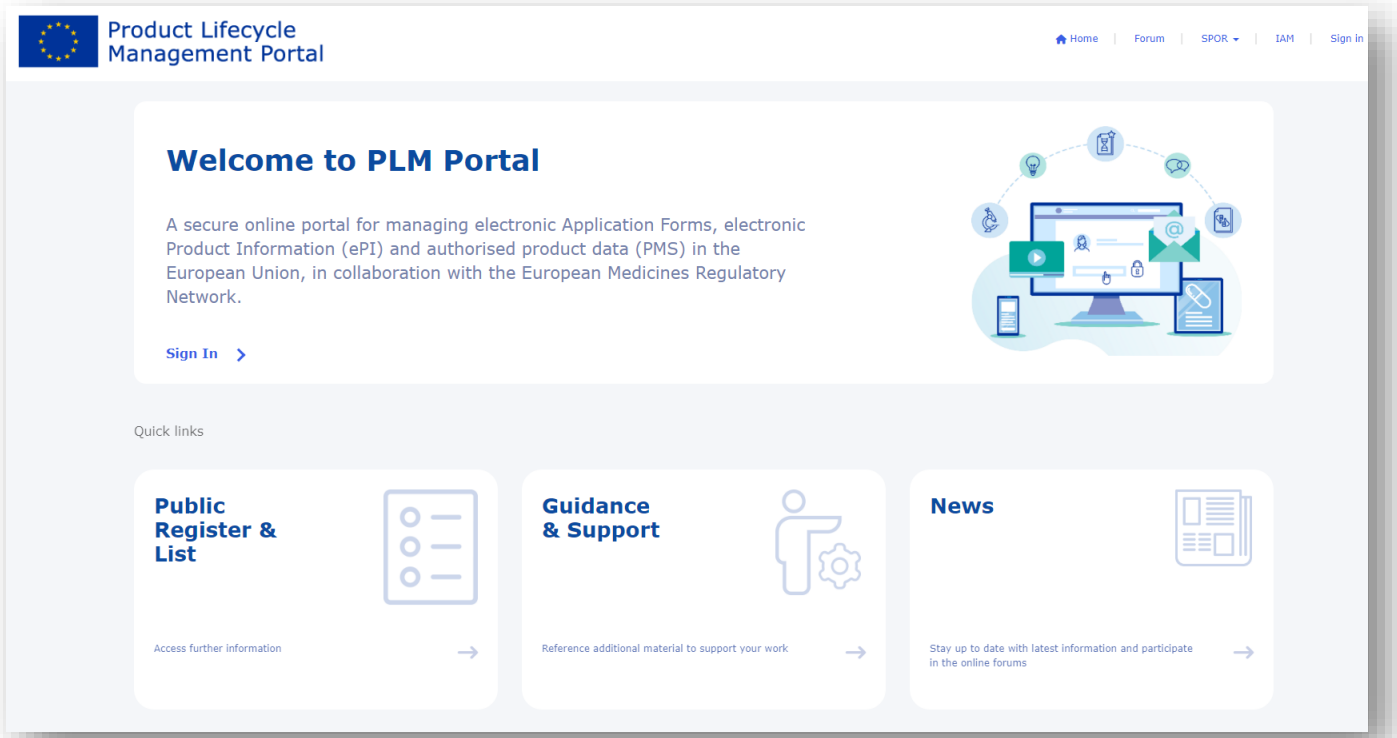
Repository and API

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

Users:
Companies
Regulators
eHealth developers

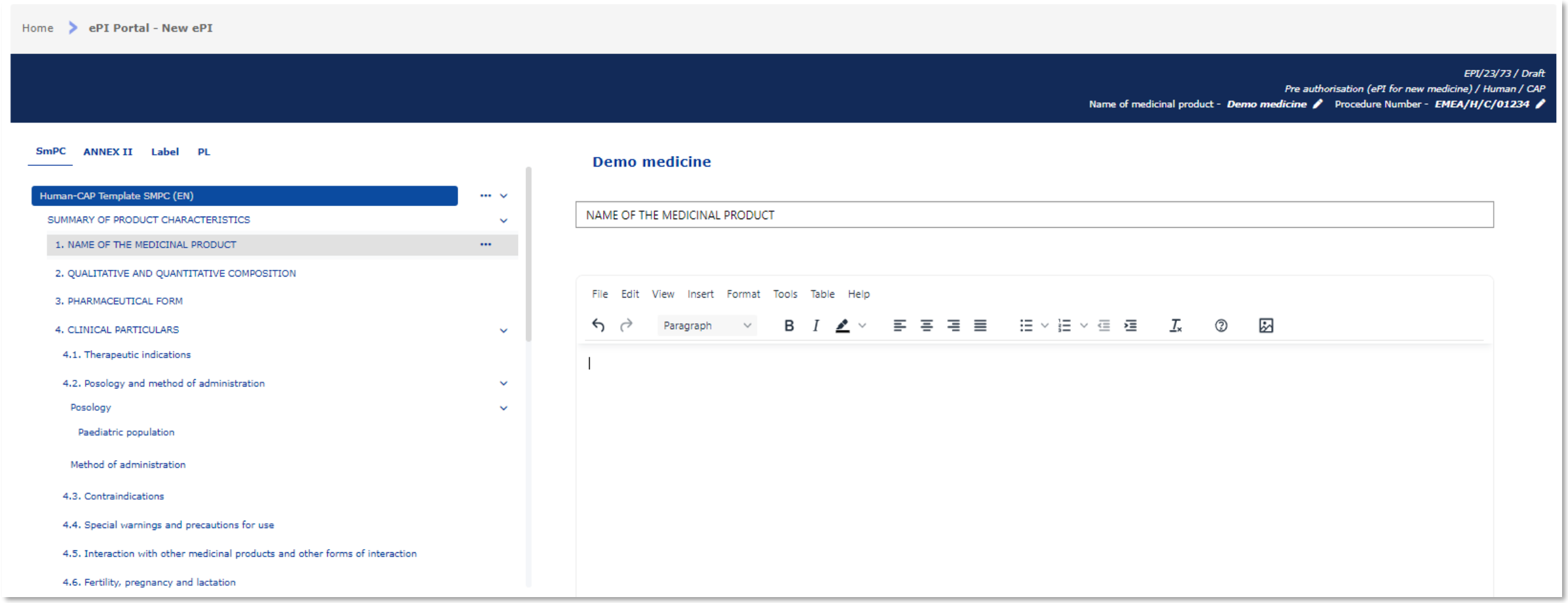
ePI MVP in PLM portal

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



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

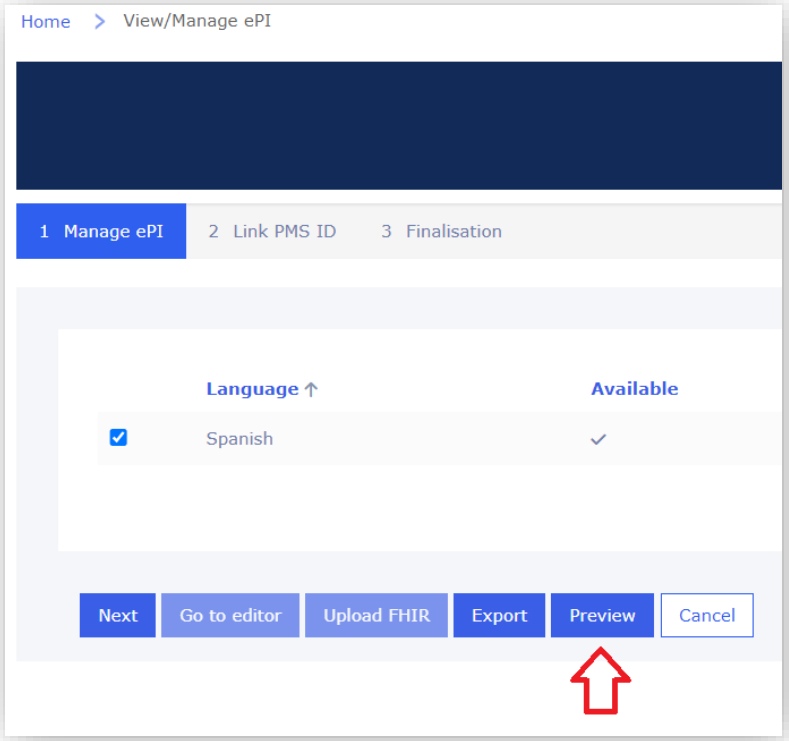
ePI editor for authoring PI documents

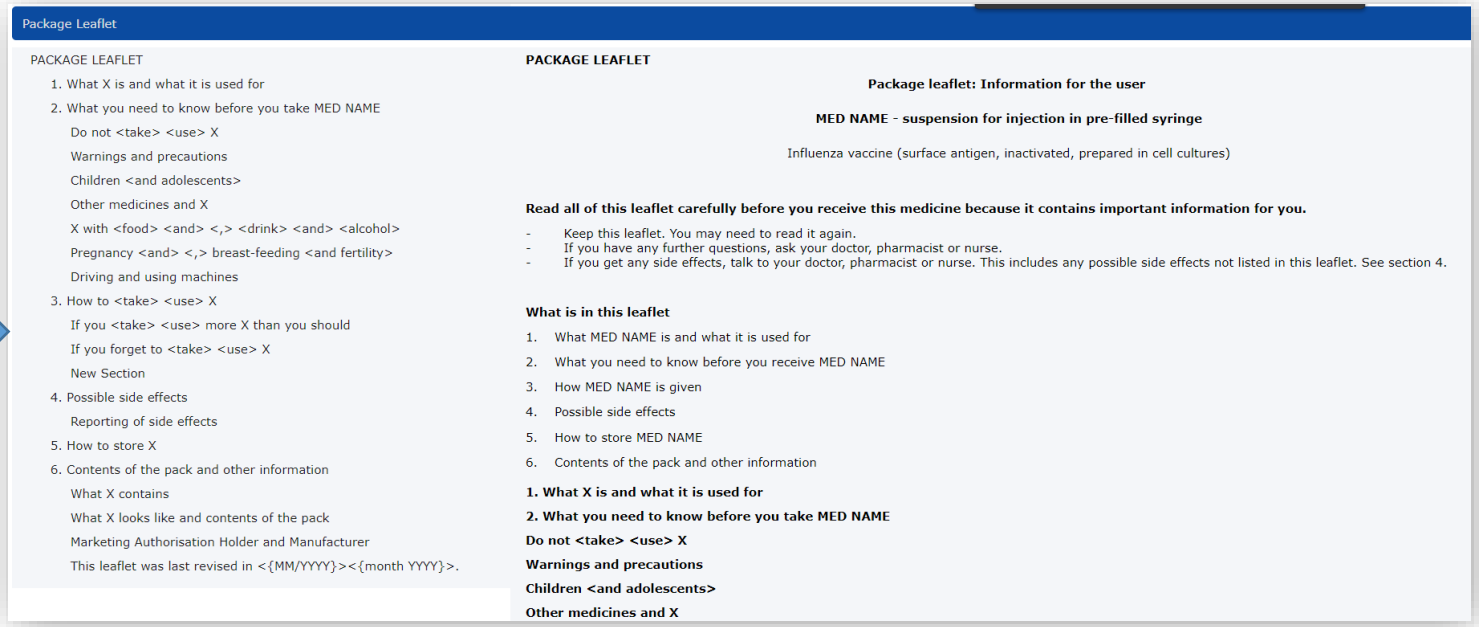


Reviewing ePIs

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

1. Via preview in ePI portal





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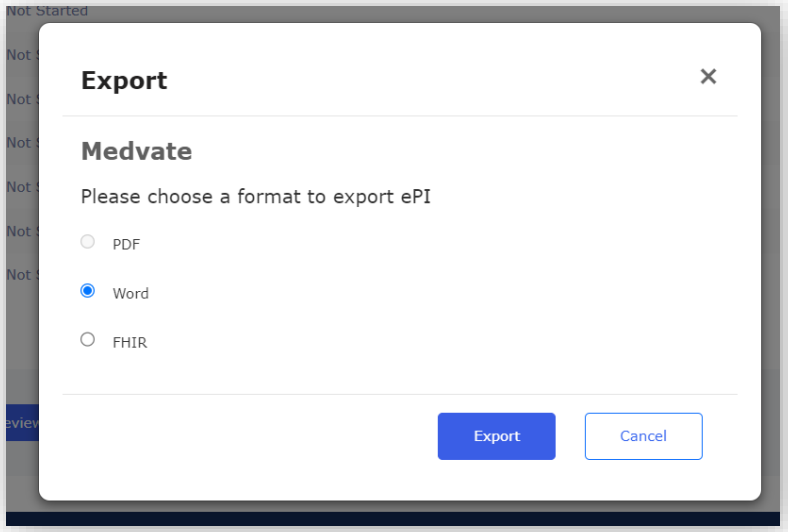
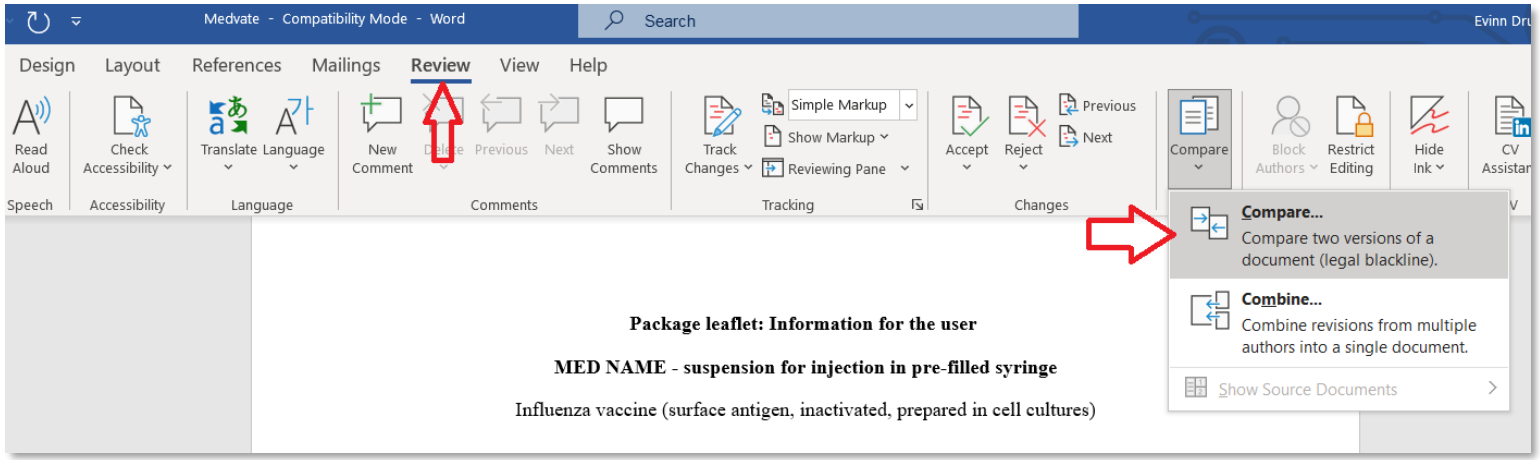
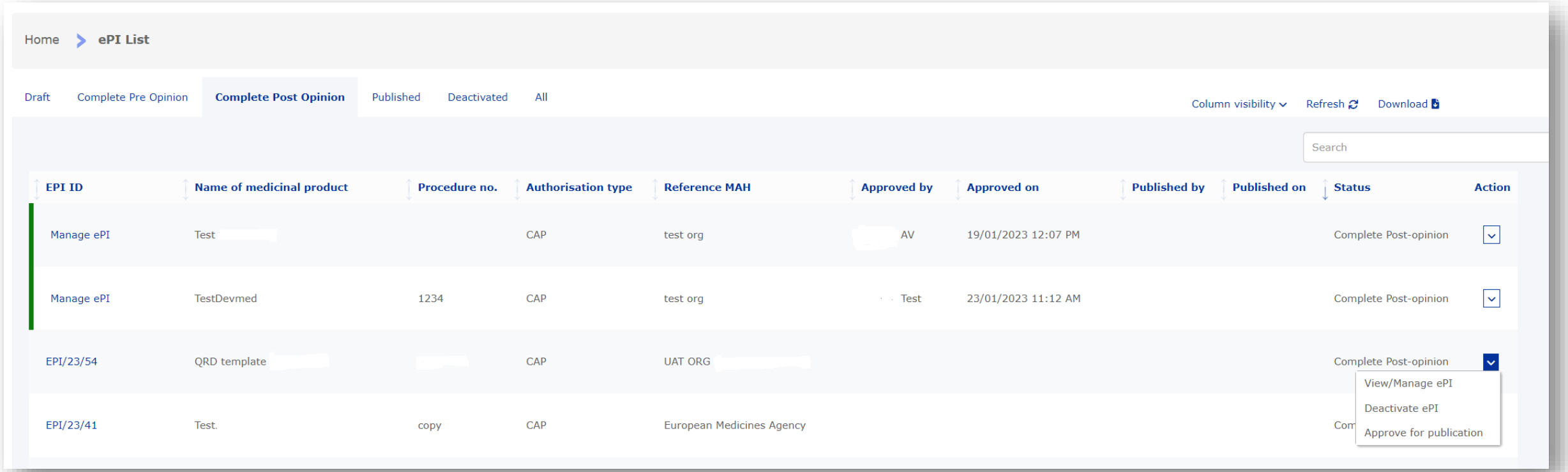
Reviewing ePIs

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



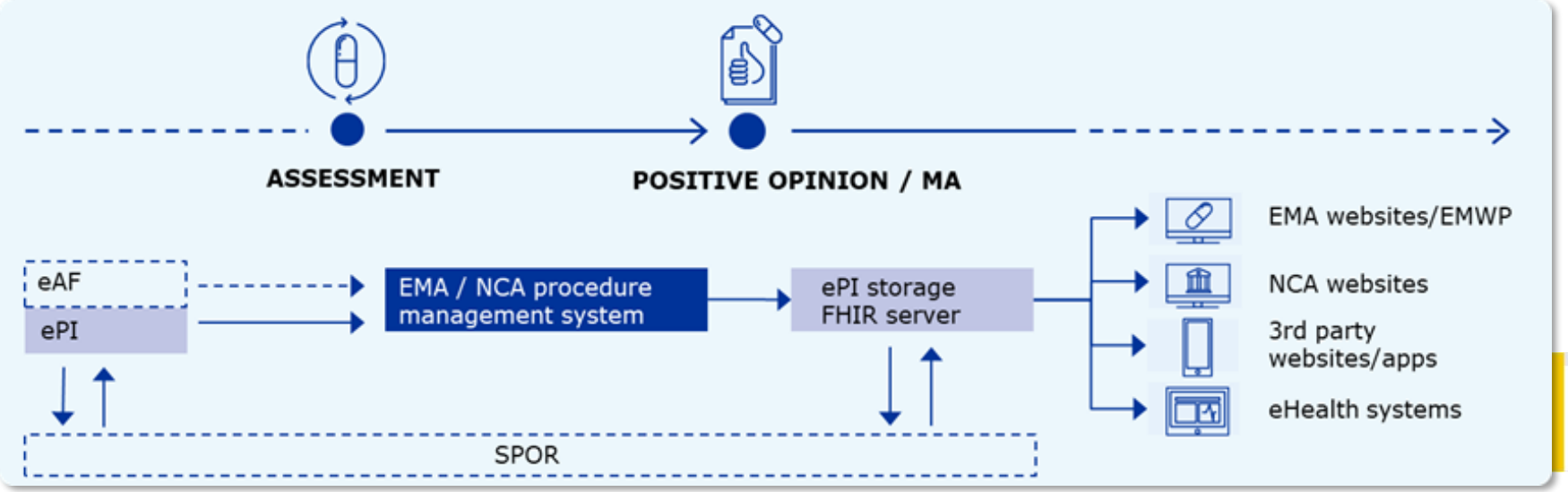


Regulator view



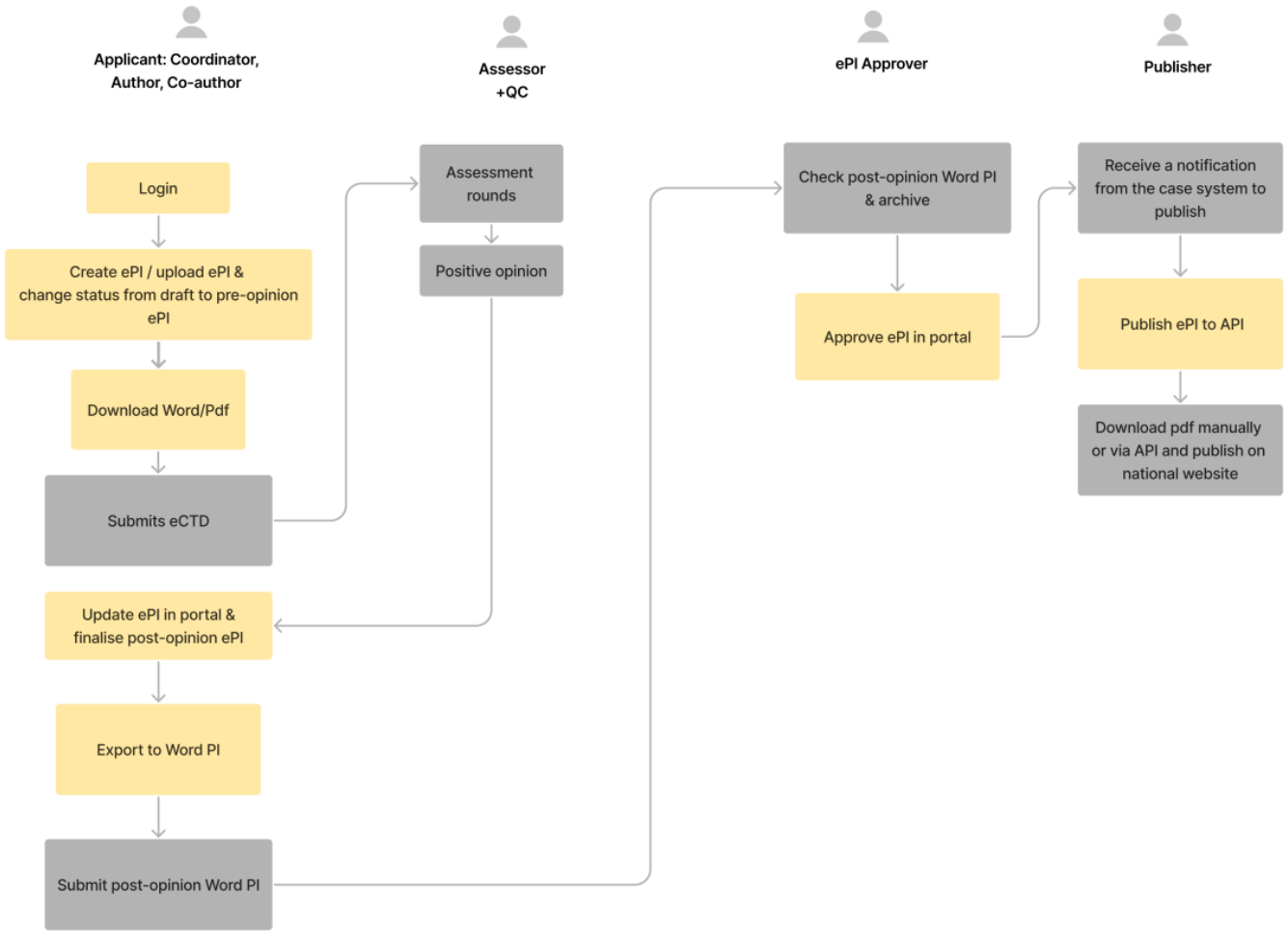
EPI Pilot Minimum Viable Product (MVP)

- 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.



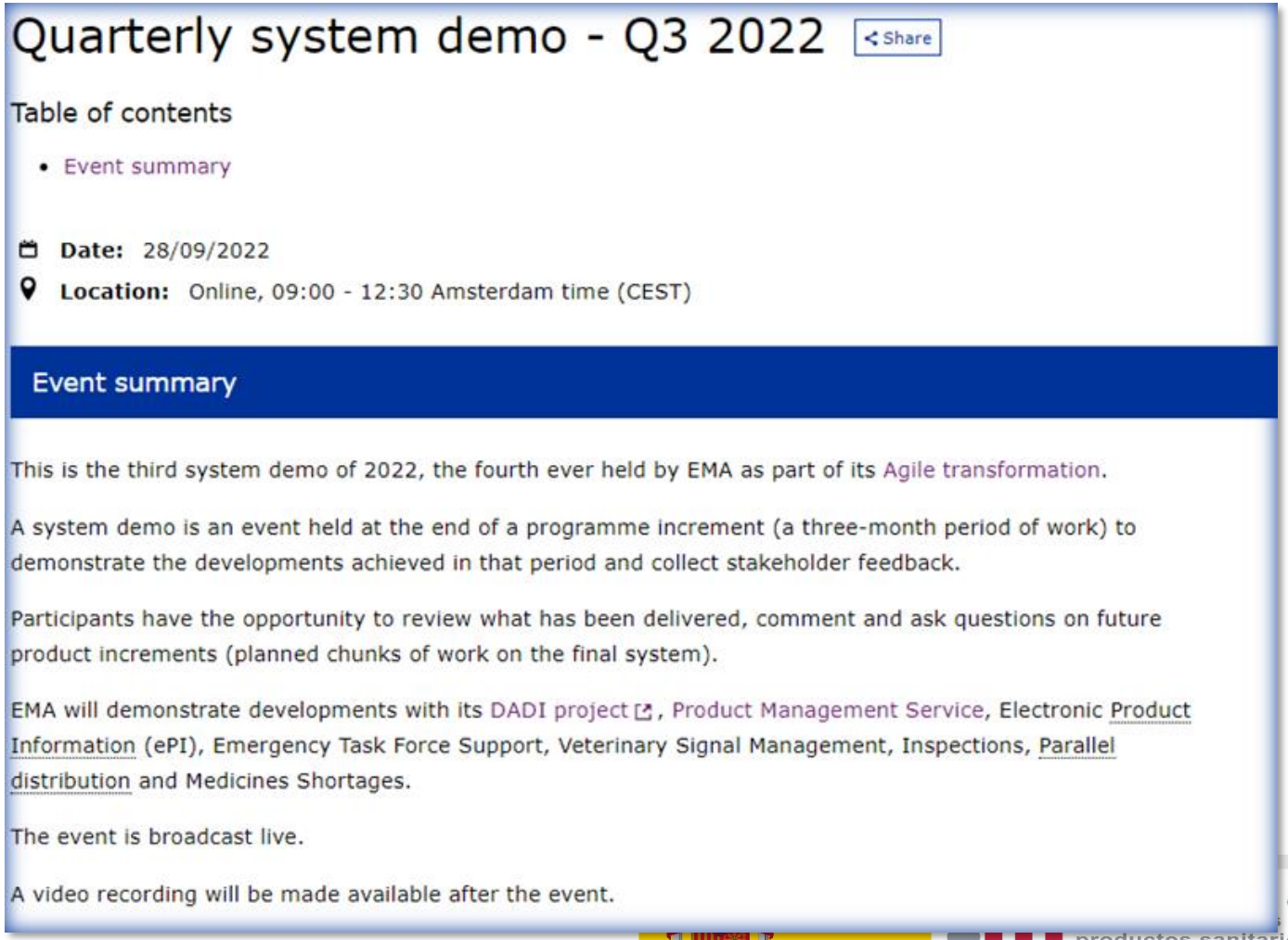
Example regulatory procedure

Pure NAP - initial



ePI System Demos

- Most recent demo 22nd 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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- Event summary

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