

PSUR assessment updates

- Updates to Q&A for assessors and Explanatory Note to GVP Module VII
- Proposed pilot on pre-filling sections of the PSUSA AR template by MAHs

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21st Industry Stakeholders platform meeting -
operation of EU pharmacovigilance | 20 October 2026

BRIEFING FOCUS

Updates to the Q&A for assessors on PSUSAs and to the Explanatory Note to GVP module VII

Proposed pilot on prefilling sections of the PSUSA AR template by MAHs

SECTION 01

Updates to the Q&A on PSUSA: Guidance document for assessors and to the Explanatory note to GVP module VII

01

Purpose and scope of this briefing

A concise overview of the updates most relevant to stakeholder awareness.

OBJECTIVE

Inform stakeholders and MAHs of the main updates in the PSUR assessment guidance package.

IN SCOPE

[**Q&A on PSUSAs: Guidance document for assessors**](#)

[**Explanatory Note to GVP Module VII**](#)

Audience lens

The Q&A is a structured document in a questions and answers format, aims to provide practical guidance to assessors.

The EN to GVP VII aims at addressing the challenges encountered during the years of running the PSUSA process.

2026: mature and operational guidance for harmonised approach within the network

The update reinforces a proportionate, evidence-based approach to PSUR evaluation and AR completion.

Q&A Guidance document for assessors

For stakeholder
awareness

- **Broader coverage:** CAPs and NAPs
- **Definitions:** common terminology for assessment
- **Assessment Report:** general guidance with section-by-section instructions
- **Aspects of amended Commission IR 520/2012** (Commission IR 2025/1466 of 22Jul25)
 - **Monitoring of EudraVigilance by MAHs**
- **Evaluation of effectiveness of aRMMs**
- **New topics:** pregnancy and breastfeeding guidance, the use of RWE and DARWIN EU studies

Document updates – EN

Section 9.4

Effectiveness of risk minimisation

GVP Modules V and XVI are explicitly referenced. The continued need for additional risk minimisation measures should be reassessed before generics/biosimilars enter the market, towards the end of data exclusivity.

Section 9.5

EudraVigilance data in PSURs

Commission IR 2025/1466 amends IR 520/2012: MAHs should monitor EudraVigilance and combine it with other available data sources. Relevant findings from monitoring EV, such as e.g. validated signals, should be reflected in the appropriate PSUR sections.

Section 11

Assessment and conclusions

Reference to [Guideline on good pharmacovigilance practices \(GVP\): Product- or population-specific considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk](#)

Pilot on pre-filling sections of the PSUSA AR template by MAHs

Pilot approach

02

Pilot on pre-filling sections of AR template by MAH

Background:

- [MAA Revamp Pilot](#) → few Applicants were asked to pre-fill the D80 non-clinical, clinical, quality AR templates with factual information (designated sections of the templates).

[Revamp pilot report - Experience gained with applicants pre-filling the factual sections of the D80 assessment reports for initial MAAs - Apr 2026](#)

- Participation in the MAA revamp pilot was **voluntary** (for Rapporteurs and Applicants).

- Presentation on the outcome of the MAA revamp pilot ([March 2026 PRAC minutes, item 12.21.1](#)), triggered discussions at PRAC to explore possibility of a similar pilot for PSUSA procedures

Pilot on pre-filling sections of AR template by MAH

Objectives and expected benefit:

Primary objectives:

- **Decreasing admin workload** for PhV assessors by copying/pasting PSUR info in the AR template → saving time for assessors to enable more focus on evaluation of the data in the PSURs
- Improving efficiency, quality of the PSUSA outcome
- Contribution to **Network sustainability**

Expected benefit for MAHs:

- Allow MAHs to clearly **highlight information** they consider most relevant for assessment in the specific sections of the AR template

Note: PSUSA AR template sections are well **defined/structured** → exercise of pre-filling sections of the PSUSA AR is expected to be **easier** for MAHs than prefilling sections of D80 MAA AR templates.

Pilot on pre-filling sections of AR template by MAH

Reminders:

- PSUSA AR templates currently not published on the EMA website
- Since Apr 2025, MAHs are required to systematically provide their **initial PSURs and RSI responses** as **Word versions (as part of the working documents folder)** :

eSubmission: Projects

PSUR Repository

PSUR Repository

The PSUR repository is a single, central platform for PSURs and related documents to be used by all regulatory authorities and pharmaceutical companies in the EU. The PSUR Repository provides an important simplification for marketing authorisation holders allowing them to send all PSURs and related submissions to a single recipient. It also facilitates the assessment by ensuring that NCAs, EMA and its scientific committees have timely and secure access to all relevant documents. The PSUR Repository was introduced by the EU pharmacovigilance legislation to facilitate the exchange of information on the safety of authorised medicines between regulators and pharmaceutical companies and it supports both the PSUR Single Assessment Procedure (PSUSA), as governed by the [EURD list](#), as well as the pure NAP procedures where the active substance(s) are outside of the EURD list.

As of 13 June 2016 the use of the PSUR Repository is **mandatory**. All PSURs for products authorised in Europe must now be submitted to the PSUR Repository (PSURs for products authorised under Art. 58 are excluded).

Since 16 April 2025, when submitting PSUR or RSI responses for a PSUSA procedure, the marketing authorisation holders (MAHs) are also required to systematically provide Word versions of the submitted PSURs and RSI responses as part of the Working Documents folder.

PSUR submissions to the Repository are made using the [eSubmission Gateway/Web Client](#) with the use of an XML delivery file. The delivery files are used to provide required metadata allowing the EMA to process the submissions. You can find the link to the tool to create the delivery file [here](#). The XML delivery file must be included within the submission package (i.e. in the relevant ZIP file).

It is essential that all MAHs, who have not previously used the eSubmission Gateway / Web Client, register to use the eSubmission Gateway as soon as possible using the [online registration form](#). Guidance on how to register can be found from the [eSubmission Gateway and Web Client online registration guidance](#) document. Existing eSubmission Gateway/Web Client users do not need to re-register.

Pilot on pre-filling sections of AR template by MAH

Considerations:

- PSUSA procedures can involve several MAHs → each MAH would need to fill in AR template with their own data → need for assessor to still copy/paste into one single AR: **it may be worth piloting for PSUSA CAPs only where 1 MAH is involved or only a few are + PSUSA NAPs where 1 MAH is involved (very few procedures)**
- PSUSA AR template with admin info on the procedure + listing of products involved can **only be generated at start date** after all MAHs' submissions/products are received and finished to be added in IRIS (1-day prior to start date) → assessor would still need to copy/paste received AR templates into the **one generated in IRIS by EMA at start date**

Pilot on pre-filling sections of AR template by MAH

Feedback received from PRAC assessors (end of Sep 2026)

- Support received from assessors on a conducting a pilot for PSUSA procedures
- Content to be prefilled in the PSUSA AR template: vast majority of the sections of the Annex in the PSUSA AR (PRAC Rapporteur/LMS comments on PSUR) i.e.:
 - ❑ **Annex section 1** (PSUR data),
 - ❑ **Annex section 2** (signal and risk evaluation),
 - ❑ **Annex section 3** (update to the RMP) if RMP submitted in a PSUSA CAP procedure involving 1 MAH
 - ❑ **Annex section 4** (benefit evaluation).
- Pilot to cover **PSUSA CAPs only** procedures and **PSUSA NAPs only where only 1 MAH** is involved in the NAP procedure
- Outside pilot, separate tables from PSUR: **Summary tabulations** and **case tables** (tables on a specific safety topic where further info is requested by PRAC/PRAC Rapp/LMS) to be provided in **Excel** format

Pilot on pre-filling sections of AR template by MAH

Proposal:

- Start a pilot in Q1 2027 (for 1 year) – exact date TBD
 - **Voluntary** participations of MAHs, but MAHs are encouraged to participate
- Apply to all **PSUSA CAPs only** (1 MAH involved or only few MAHs)
 - Apply to about **10 PSUSA NAPs only** (in which 1 MAH only is involved in the procedure)
- Pre-filled part of AR template to be provided as part of **working documents folder** (like for Word PSURs), with initial PSUR submission
 - Specific information on the pilot to be published in Q4 2026 on PSUR Repository eSubmission webpage

Outside pilot

New proposed requirement:

- **Summary tabulations** and **case tables** (tables on a specific safety topic where further info is requested by PRAC/PRAC Rapp/LMS) to be provided in **Excel format** outside eCTD/PSUR Repository
- Apply to all **MAHs of PSUSAs (all PSUSA CAPs, mixed CAP/NAPs, and NAPs only)** for all upcoming PSUSAs
- Specific information on this new requirement to be published in Q4 2026 on PSUR Repository eSubmission webpage

Pilot on pre-filling sections of AR template by MAH & new requirement for Excel tables submissions

Proposed Timelines

