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).

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.

News

Previous news can be found here.

24-05-2022

PSUR Repository MAH user interface - technical update

The PSUR Repository team has been working on an update of the framework for the user interface. This is a technical update only providing a slightly different look and feel. It should also be noted that the option to select submission format NeeS has been disabled in the view of **mandatory use of eCTD for all procedure types since 1st January 2019**. There are no other functional changes to the MAH user interface. The updated user interface will be deployed in production once the internal user acceptance testing has been finalised (exact date TBC).

An updated user guide and release notes will be published at the time of the go live.

16-01-2021

Due to the end of the Brexit transitional period on 31st of December products authorised in the UK are no longer available for selection in the PSUR Repository delivery file. More information is available in the guidance to applicants with regards to impact of Brexit; https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/practical-guidance-procedures-related-brexit-medicinal-products-human-veterinary-use-within_en.pdf

Please note that all data submitted for single assessment of periodic safety update reports (PSUSA), including data submitted before the withdrawal date on UK nationally approved products, will be considered during the assessment. However, after the transition period, UK products will formally no longer be part of any ongoing PSUSA procedure. Therefore, after the transition period assessment reports will no longer be shared with marketing authorisation holders for UK products that were previously concerned by the PSUSA procedure. The outcome of the PSUSA procedure will only concern products authorised in the Union (EEA).

As the products that can be included in the PSUR procedures (irrespective of whether they are part, or not, of an EU single assessment procedure), are retrieved from the Art. 57 database, only those UK nationally authorised products for which the authorisation country in the Art. 57 entry has been updated to 'United Kingdom (Northern Ireland)' will be available for selection.

Those UK nationally authorised products that have not been updated in the Art. 57 database and still refer to authorisation country 'United Kingdom', are not be available for selection in the product lists from 1 January 2021. Therefore, the marketing authorisation holders must update their entries in art. 57 database in line with the new status of the products after 31 December 2020 before submitting a PSUR for an UK nationally authorised product with respect to Northern Ireland, irrespective of whether the PSUR is part or not of an EU single assessment procedure.

If you wish to submit a PSUR or responses and the product is not available in the PSUR Repository, the following changes must be made in the Art. 57 database:

- The product authorisation country code must be updated to UK (Northern Ireland) with new country code XI for UK(NI)
- The MAH country needs to be in EEA or UK (Northern Ireland)

15-12-2020

A new version of the PSUR Repository (industry and NCA user interfaces) is now available. Minor changes have been introduced to both industry and NCA user interfaces due to the end of the Brexit transitional period on 31st of December.

The changes relate to use of terms United Kingdom (Northern Ireland) and new country code XI for UK(NI) in the product selection tables in the industry user interface.

09-06-2020

A new version of the PSUR Repository (industry and NCA user interfaces now available

An updated version of the PSUR Repository (v1.17.0.0) is now available. This release provides minor changes to the MAH and NCA user interfaces, new features for EMA users and number of new notifications for all users. Details of the changes are available in the updated NCA and MAH User Guides, the PSUR Repository Training Guide for MAHs and NCAs and the updated Release Notes.

Announcements

Announcement on the mandatory use of the PSUR repository

PSUR Repository Bulletin

Previous Repository Bulletins are available here.

User Documents

***** Presentations and webinars have been developed during the transitional period, prior to the mandatory use of the system and may refer to national submission requirements. All users should note that the use of the PSUR Repository is now mandatory and all PSURs must be submitted to the PSUR Repository only. The national submission requirements **no longer apply**. PSURs submitted directly to National Competent Authorities only will be excluded from the PSUR assessment procedure.

PSUR Repository user registration form for NCA users	Repository user registration
MAH PSUR Repository User Guidance document	MAH user guide (09.06.2020)
NCA PSUR Repository User Guidance document	NCA user guide (09.06.2020)
How to send submissions via the Web Client – User Guide	User guide (22-06-2020)
PSUR Repository FAQ document	Frequently Asked Questions
Mandatory use Questions and Answers document for MAHs	MAH Q&As (24.0.2016)
Release Notes	Release notes 15.12.2020) **Updated**
PSUR repository presentation on changes on Brexit related changes – v.1.17.3.0	**Presentation (15.12.2020) New**
PSUR Repository training for MAHs and NCA on new functionality –v1.17.0.0*	Presentation (09.06.2020)
PSUR Repository training for MAHs and NCA on new functionality –v1.16.0.0*	Presentation (09.10.2019)
PSUR Repository training for MAHs on new functionality – v1.07.00*	Presentation(25.07.2016)
PSUR Repository training for MAHs on new functionality – v1.06.00*	Presentation (17.05.2016)
PSUR Repository interactive Q&A session with MAHs – v1.06.00*	Presentation (24.05.2016)
PSUR Repository training for MAHs on new functionality – v1.04.00*	Presentation (14.10.2015)
PSUR Repository interactive Q&A session with MAHs – v1.04.00*	Presentation (28.10.2015)
PSUR Repository for MAH - New functionality v1.03.00	Presentation (12.08.2015)
PSUR Repository interactive Q&A session with MAHs – v1.03.00	Presentation (10.09.2015)
How to submit to PSUR Repository - existing Gateway users	Presentation
How to submit to PSUR Repository – New Gateway users	Presentation
Slides and the Q&A from 21 May webinar	Slides and Q&A's
Formatted table template	Download
EudraVigilance system downtime – impact on PSUR Repository and the eAF	Document (05.10.2017)
Multimedia Tutorials	
PSUR Repository training for MAHs on new functionality – release v1.07.00)	Multimedia webinar (25,07.2016)
Webinar on the mandatory use of the PSUR Repository for MAHs	Multimedia webinar (13.06.2016)
Webinar on the mandatory use of PSUR Repository for NCA users	Multimedia webinar (13.06.2016)
PSUR Repository training for MAHs on new functionality – release v1.06.00)*	Multimedia webinar (17.05.2016)
PSUR Repository – interactive Q&A session for NCAs on new functionality – release v1.06.00*	Multimedia webinar (26.05.2016)
PSUR Repository training for NCA users on new functionality – release v1.06.00 *	Multimedia webinar (17.05.2016)
PSUR Repository training for MAHs on new functionality – release v1.04.00)	Multimedia webinar (14.10.2015)
PSUR Repository training for NCA users on new functionality – release v1.04.00	Multimedia webinar (15.10.2015)
PSUR Repository interactive Q&A session with MAHs – release v1.04.00	Multimedia webinar (28.10.2015)
PSUR Repository training for MAHs on new functionality (v1.03.00)	Multimedia webinar (12.08.2015)
PSUR Repository training for NCA users on new functionality (v1.03.00)	Multimedia webinar (13/08/2015)
PSUR Repository interactive Q&A session with MAHs – release v1.03.00	Multimedia webinar (10.09.2015)
How to submit PSURs training for existing Gateway users	Multimedia webinar

How to submit PSURs training for new Gateway users	Multimedia webinar
How to submit to PSUR Repository – pilot training for MAH	Multimedia webinar
Pilot training for NCA users	Multimedia webinar
Technical Documents	
Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs	Specifications of the PSUR Repository API - (17.10.2016)
Supplementary Specification	Additional email notifications specification
Who to contact	
MAH Gateway user registration	https://servicedesk.ema.europa.eu
NCA User registration	https://servicedesk.ema.europa.eu
Gateway submission related technical issues	https://servicedesk.ema.europa.eu
All questions related to the PSUR Repository, submission of PSURs, non-procedural issues with PSUSA and questions related to training, user guide or documentation on this page	https://servicedesk.ema.europa.eu
PSUR procedural questions for the EU Single Assessment coordinated by the Agency. **1**	PSUR procedural guidance Q&A

1.Please note that procedural questions on non-EU single assessment procedures conducted only in one Member State must be addressed to the relevant National Competent Authority.

As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.

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