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Periodic Safety Update Report (PSUR) repository mandatory use: questions and answers

Information for Marketing Authorisation Holders on how to submit a PSUR

**1. What is the PSUR repository?**

The PSUR repository is a common storage place for the PSURs, the regulators’ PSUR Assessment Reports (ARs), comments and final outcomes. National Competent Authorities (NCAs) have direct, secure access to the repository. More information on the PSUR repository can be found here: <http://esubmission.ema.europa.eu/psur/psur_repository.html>.

**2. How are PSUR submissions changing and how does this affect marketing authorisation holders (MAHs)? Rev. June 2016**

From 13 June 2016, it is mandatory for all MAHs within the European Economic Area (EEA) to submit PSURs for human medicines directly to the PSUR repository. This means that companies have to use the repository as a single point for all submissions and should no longer submit PSURs to NCAs directly. This requirement also applies to the submission of supplemental information, even if the original PSUR submission was only submitted via CESP or other means to a National Competent Authority.

The PSUR repository is mandatory for both centrally and nationally authorised medicines whether they follow the EU single assessment or a purely national assessment procedure. The PSUR repository is intended for PSURs for human medicines only. The EMA PSUR post-authorisation guidance and CMDh SOP have been updated to this effect. The CMDh document “Requirements on Submissions for Periodic safety update reports (PSUR) to National Competent Authorities (NCAs) for products authorised via National Procedures, MRP and DCP (NAPs)” will no longer be relevant after the 13 June 2016. The abolishment of national requirements also covers the requirement of submissions of hard copy cover letters with wet signatures to NCAs.

Related information: [CMDh SOP on the processing of PSUR single assessment for nationally authorised products](http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Pharmacovigilance_Legislation/PSUR/PSUR_Single_assessment/CMDh_322_2014_Rev01_-_2015_03_-_clean.pdf) | [Periodic safety update reports: questions and answers](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d)

**3. After 13 June 2016, what happens if a PSUR is not submitted to the PSUR repository?**

PSURs that have not been sent to the PSUR repository are considered as not submitted and will not be assessed. PSURs not sent to the PSUR repository will not fulfil the MAH’s legal obligation to submit PSURs.

**4. For which medicines must a PSUR be submitted?**

PSURs are intended to provide a safety update on a medicine to allow a regular assessment of its balance of benefits and risks. They have to be submitted by MAHs to the regulatory authorities for an assessment at defined time points after a medicine has received a marketing authorisation.

PSURs have to be submitted for all medicines which are included in the EURD (European Union reference dates) list: [List of EU reference dates and PSUR submission](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910).

For medicines not included in the EURD list, PSURs should be submitted as specified in the marketing authorisation or otherwise according to the standard submission schedule of PSURs (i.e. six-month intervals, yearly and thereafter 3 yearly).

Related information: [Periodic safety update reports: questions and answers](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d) | [List of EU reference dates and PSUR submission](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910)

**5. For which medicines do MAHs not need to submit a PSUR?**

Routine PSURs are normally not required for the following types of medicines:

* Medicines containing a well-established substance (authorised in accordance with Article 10a of Directive 2001/83/EC)
* Homeopathic medicines (authorised in accordance with Article 14 of Directive 2001/83/EC)
* Traditional herbal medicines (authorised in accordance with Article 16a of Directive 2001/83/EC)
* Generic medicines (authorised in accordance with Article 10(1) of Directive 2001/83/EC)

National Competent Authorities can however request PSUR for generic medicinal products at any time on the grounds detailed in Article 107c (2) of the Directive.

All MAHs should check [the EURD list](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500133159) to confirm if the PSUR is required for products authorised in accordance with Articles 10(1), 10a, 14 and 16a of Directive 2001/83/EC.

The obligation to submit to the PSUR repository does not apply to products that have been granted a scientific opinion under Article 58 of Regulation (EC) No 726/2004. For further information on how to submit PSURs for Article 58 products please refer to the guidance on Dossier requirements for Centrally Authorised Products (CAPs).

Related information: [Dossier requirements for Centrally Authorised Products (CAPs)](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf) | [Periodic safety update reports: questions and answers](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d)

**6. How do I submit a PSUR?**

All PSURs are submitted to EMA’s PSUR repository using the eSubmission Gateway/ Web Client: <http://esubmission.ema.europa.eu/esubmission.html>. The required submission format is eCTD (mandatory for all centrally authorised products) or non-eCTD electronic submission (NeeS). PSURs submitted in any other electronic format cannot be uploaded into the PSUR repository and will be rejected. In order to submit a PSUR to the PSUR repository via the eSubmission Gateway / Web Client all users must register using the [self-registration functionality](https://esubregistration.ema.europa.eu/registration/). Further information on how to register can be found on the following link: [How to register for the Web Client](http://esubmission.ema.europa.eu/gateway/Web%20Client%20online%20registration%20user%20guidance%20-%20PRODUCTION.doc). Useful information on the eSubmission Gateway and the Web Client including guidance and multimedia tutorials for MAHs can be found on the [eSubmission Gateway website](http://esubmission.ema.europa.eu/esubmission.html).

Useful information on the PSUR repository, guidance on how to register and multimedia tutorials for MAHs on how to submit a PSUR, can be found on the [PSUR repository website](http://esubmission.ema.europa.eu/psur/psur_repository.html).

Related information: [How to register for the Web Client](http://esubmission.ema.europa.eu/gateway/Web%20Client%20online%20registration%20user%20guidance%20-%20PRODUCTION.doc) | [eSubmission Gateway and eSubmission Web Client](http://esubmission.ema.europa.eu/esubmission.html) | [PSUR repository website](http://esubmission.ema.europa.eu/psur/psur_repository.html) | [eSubmission Registration](https://esubregistration.ema.europa.eu/registration/)

**7. What steps do I have to take before I can submit a PSUR to the PSUR repository?**

Prior to submission to the PSUR repository, MAHs must ensure that the information on their authorised medicines is entered correctly in the Article 57 database. This is a legally binding requirement from the EU pharmaceutical legislation.

The PSUR repository product selection functionality is connected to the Article 57 database; therefore if an MAH experiences any issues with the product selection in the PSUR repository while creating the delivery file, they should ensure that the product has been correctly included in the [Article 57 database](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0). It is very important to ensure that all Article 57 database entries are correct with the products containing the correct legal basis. The PSUR repository has built-in business rules which prevent products with incorrect legal basis being displayed.

All PSURs should be submitted together with a delivery file which will provide metadata for the submission. The delivery file can be created on the [PSUR repository MAH user interface](https://psur-repo.ema.europa.eu/psur-ui/prepare/submission.html). Detailed guidance on how to create and include the delivery file in your submission can be found from the [MAH user guide](http://esubmission.ema.europa.eu/psur/docs/PSUR%20Repository%20user%20guide%20for%20MAH%20submissions.pdf) and from the [PSUR repository website](http://esubmission.ema.europa.eu/psur/psur_repository.html).

Related information: [PSUR repository website](http://esubmission.ema.europa.eu/psur/psur_repository.html) | [Data submission of authorised medicines in the European Union](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/02/WC500182751.pdf) | [Article 57 database](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0)

**8. I cannot find my products in the PSUR repository user interface.**

If a MAH cannot find their product in the PSUR repository this will most likely be due to the fact that the product has not been correctly included in the Article 57 database. MAHs should review the database entry to ensure the product has been correctly included. If the MAH continues to encounter issues they should contact the [EMA Service Desk portal](https://servicedesk.ema.europa.eu/).

**9. I cannot find my procedure number for the EU single assessment in the listing provided in the PSUR repository user interface.**

The PSUR repository has been designed in such a way that MAHs can submit their PSURs only in the time window between the data lock point (DLP) and the EURD submission deadline. Any attempt to submit outside of this window will lead to the MAH not been able to find the procedure number. These business rules only apply however to the single assessment (PSUSA) procedure. For the non-EU Single Assessment there is no PSUSA Procedure number, and as such no requirement to include it when creating the XML delivery file. If the MAH continues to encounter issues they should contact the [EMA Service Desk portal](https://servicedesk.ema.europa.eu/).

**10. What are the requirements regarding the accompanying cover letter for PSUR submissions?**

Any PSUR in the EU Single Assessment Procedure needs to be submitted together with the EMA [template table cover letter](http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2011/05/WC500106371.doc) as detailed in the [Periodic safety update reports: questions and answers](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d). Marketing Authorisation Holders are recommended to also use this cover letter to accompany submission of purely national PSURs to the PSUR repository.

MAHs should be reminded that only products selected via the user interface will be considered as part of the procedure.

Related information: [template table cover letter](http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2011/05/WC500106371.doc) | [Periodic safety update reports: questions and answers](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d)

**11. How can I submit my PSURs if there is a planned or unplanned downtime of the PSUR repository?**

If a MAH encounters an issue with the PSUR repository they should immediately report the incident through the [EMA Service Desk portal](https://servicedesk.ema.europa.eu/).

As soon as the EMA is aware of a system failure a communication to the EU Network will be launched and information published on the eSubmissions website and on the EMA Service Desk Portal. Status updates will be provided at regular time points, and the EMA will issue recommendations regarding the upload of procedural documentation and submission of PSURs. The system has built-in functionality to allow for the late submissions.

**12. Who can I contact to help me with my queries on PSUR repository?**

Users can contact the EMA to send their questions or report any issues they have with the PSUR repository and/or the eSubmission Gateway/ Web Client to the EMA Service Desk portal: <https://servicedesk.ema.europa.eu>