



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# PSUR Repository

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Changes introduced in v1.17.0.0





## Changes relating to MAH functionality

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- Start of procedure notification to MAH (SD-296799)
- Message - required submission format is eCTD (SD-258305)
- Available submission units (SD-220976)
- Procedure closed for submission after PRAC outcome (SD-277152)

## Confirmation of start of procedure for haemophilus type b and meningococcal group c co..., \*IT\*, PSUSA



PSUR-REPO-TEST@ema.europa.eu

To  
Cc: Dhiman Vikas; Loukeri Pinelopi

Reply Reply

### Action Items

Dear MAH contact person,

Please be informed that the above procedure started and will follow the below timetable:

Start of procedure:	01/05/2020
PRAC Rapporteur's/Lead Member State's preliminary assessment by:	05/05/2020
PRAC Rapporteur's/Lead Member State's and MAH comments on the Lead Member State preliminary assessment by:	10/05/2020
PRAC Rapporteur's/Lead Member State's updated assessment report by:	05/06/2020
PRAC recommendation:	10/06/2020

### Note to MAH:

Amendments to the EURD list entries such as changes of PSUR submission frequency can be proposed in the frame of this PSUSA procedure.

Such requests should be duly justified and can be included as part of the MAH's comments to the preliminary assessment report by the deadline specified in the above timetable. The requests have to be made using the specific template published on the EMA website ["Requests for amendments of the EU reference dates list"](#).

Please note that changes in the EURD list come into force 6 months after its publication. Therefore, the frequency amendment will become effective from the PSUR that follows the publication.

For more details on how to submit amendments to the list, please refer to the [EURD list Introductory cover note](#).

Should the MAH contact details for this procedure change, please contact us immediately and provide us with the updated information.

Should you have any queries, please do not hesitate to contact me or the procedure manager Pinelopi Loukeri by email [pinelopi.loukeri1@ext.ema.europa.eu](mailto:pinelopi.loukeri1@ext.ema.europa.eu).

Please note that for future communication on this procedure an Eudralink account is required.

You can find the guidance here:

<https://eudralink.ema.europa.eu/EudraLink-User-Guide.pdf>

For help with requesting an account please contact my colleagues via <https://servicedesk.ema.europa.eu>

A new automated notification including the procedure timetable is sent to the MAHs.

The email addresses used, are those that were provided in the email field in the XML delivery file at the time of the submission



Please note that it is now mandatory to submit all PSURs in eCTD format. Submission of PSURs or supplemental information in any other electronic format may lead to rejection. For more information, please see the [eSubmission website](#).

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**Submission type:\*** PSUSA  
 Subject to or related to a si

**Submission unit :\*** initial

\*Denotes mandatory field

EU-Single assessm



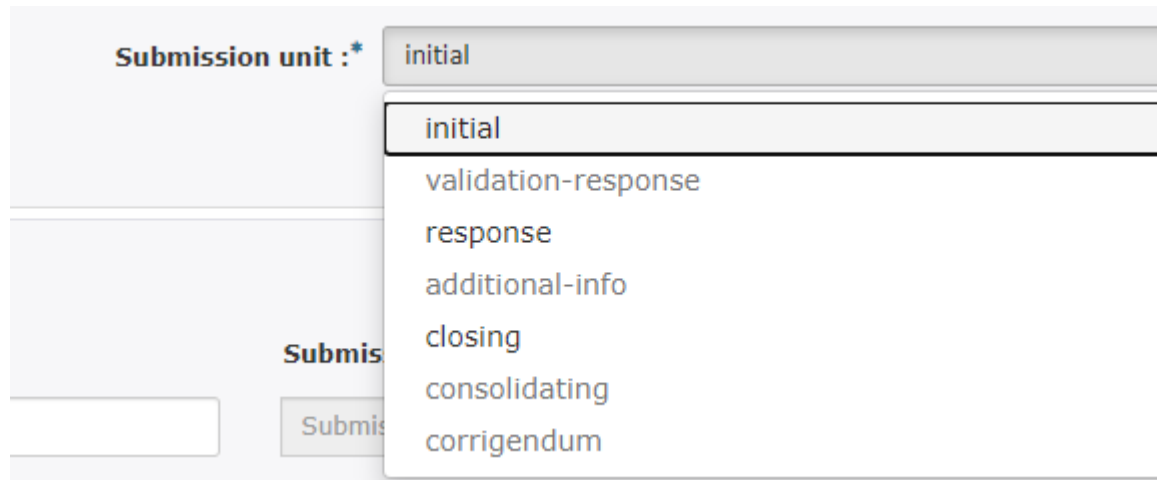
A new reminder on the mandatory use of eCTD has been added to the PSUR User Interface.

The text contains a hyperlink to the eSubmissions website where more information on eCTD can be found.

Submission units 'initial', 'response' and 'closing' are available for selection.

The following submission units 'validation-response', 'additional-info', 'consolidating' and 'corrigendum' are now greyed-out from the drop-down list, as they are not relevant for PSUR submissions.

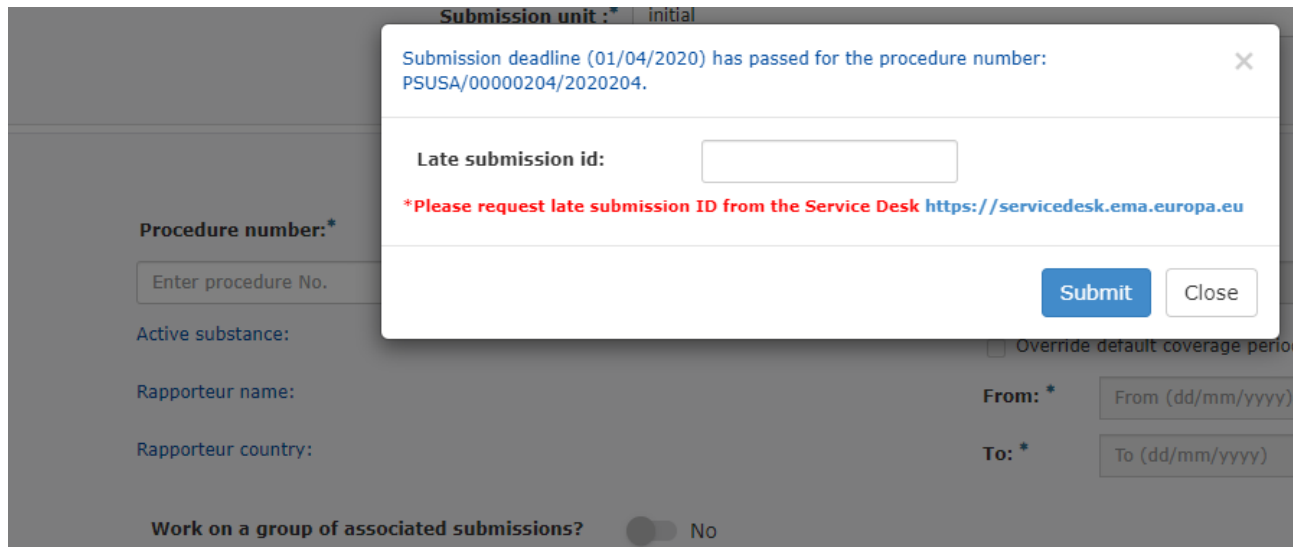
Submission unit 'Response' cannot be selected if no initial PSUR has been submitted for the procedure in question.



When the submission deadline has passed for the selected procedure, a pop-up window will appear where user will be prompted to provide the late submission ID for the procedure with an **added** note: "Please request late submission ID from the Service Desk

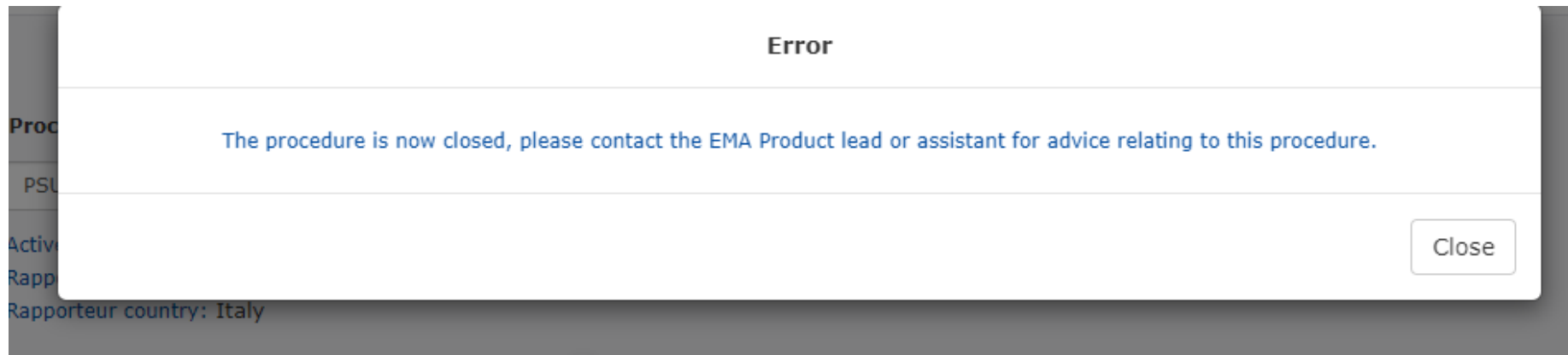
<https://servicedesk.ema.europa.eu>"

Submission unit 'Response' cannot be selected if no initial PSUR has been submitted for the procedure in question.



For PSUSA procedures, once the PRAC outcome has been adopted, the procedure is closed for new submissions (PSURs and responses).

Submission of 'closing sequence' remains possible for closed procedures.



The screenshot shows a software interface with a sidebar on the left containing menu items: 'Proc', 'PSU', 'Activ', 'Rapp', and 'Rapporteur country: Italy'. The main content area displays an error message with the following text:

**Error**

The procedure is now closed, please contact the EMA Product lead or assistant for advice relating to this procedure.

[Close](#)



## Changes relating to NCA functionality

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- Procedure closed for AR and Comment uploads after PRAC outcome (SD-277152)
- Renamed product list attachments in PSUR Repository notifications (SD-303713)
- Cancelling and revoking cancellation for non starter procedures (SD-79991)



For PSUSA procedures, once the PRAC outcome has been adopted, the procedure is closed for new uploads of preliminary and updated assessment reports and comments.

MAHs are no longer able to submit PSURs and responses for closed procedures.

## Error

The procedure is now closed, please contact the EMA Product lead or assistant for advice relating to this procedure.

Close

The product listing attachments in the PSUR Repository notifications have been renamed from 'Products' to correspond with the subject line of the notification, for example "PSUR blinatumomab, CZ, PSUSA00010460201906, 02062019".

There are no special characters in the attachment name as these require further renaming.

PSUR gaxilose, \*IT\*, PSUSA/00010283/202001, 26/01/2020



PSUR-REPO-TEST@ema.europa.eu

To

[Redacted recipient email address]



PSUR gaxilose, IT, PSUSA00010283202001, 26012020.xlsx  
6 KB



PSUSA number: PSUSA/00010283/202001

Data Lock Point: 26/01/20 00:00

Submission deadline for the procedure was 24/04/2020

Active substance: gaxilose



- The EMA admin users are now able to cancel and revoke a cancellation for a non-starting procedure. The reason for cancellation will be provided in the notification to the NCAs.
- Once the procedure is cancelled, the automated reminder notifications to upload the assessment report will no longer be sent to the LMS (Lead Member State).
- The PSUR start of procedure notification – no PSUR received will be disabled for **NAP only PSUSA procedures**.



# Thank you for your attention

## Further information

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[Kristiina.Puusaari@ema.europa.eu](mailto:Kristiina.Puusaari@ema.europa.eu) or [Hanna.Palyszka@ema.europa.eu](mailto:Hanna.Palyszka@ema.europa.eu)

### **European Medicines Agency**

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**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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