swissmedic

Information from Swissmedic regarding changes to the procedure for submitting PSUR (Periodic Safety Update Reports) and PBRER (Periodic Benefit-Risk Evaluation Reports)

PSUR / PBRER added to Swissmedic Portal

From summer 2016, Swissmedic Portal users will also be able to use the Portal to track the progress of applications for the assessment of PSUR / PBRER for their medicinal products.

As a result, confirmations of receipt will no longer be sent to Portal users since they will be unnecessary.

Authorisation holders who do not have access to the Swissmedic Portal will continue to receive confirmations of receipt.

«PSUR / PBRER form for human medicines» modified

MU103_20_001e_FO PSUR / PBRER form for human medicines

With the addition of PSUR / PBRER to the Swissmedic Portal, a few modifications have been made to the «PSUR / PBRER form for human medicines».

- The legal representative is now inserted on the form.
- The «Received by Swissmedic» and «Notice of receipt by Swissmedic» boxes have been deleted.
- The Responsible Person no longer needs to sign.
- Minor changes have been made to bring the form into line with the Swissmedic layout.
- Until now it has not been necessary to complete the «PSUR / PBRER form for human medicines» for certain periodic safety reports (e.g. «Annual Safety Report») if there was a safety signal. The reason had to be stated in the covering letter.

  To avoid uncertainty, a new item has been added to the «Reasons for submitting this PSUR» section.

  ☐ Periodic Safety Report as risk-minimisation measure (e.g. as additional requirement by a regulatory authority)

  ☐ Other: ……