

Periodic Safety Update Report [PSUR]

A Periodic Safety Update Report (PSUR) is EU terminology for a Periodic Benefit Risk Evaluation Report (PBRER). It is produced by the marketing authorisation holder (the individual or business that is granted authorisation to market a medicine) at defined time points after a medicine has been given marketing authorisation.

The purpose of the report is to provide comprehensive and up to date information about the safety of a medicine. The report should summarise any new evidence on safety, efficacy and effectiveness that might affect the balance of risks and benefits. The PSUR communicates about risk to regulatory authorities and identifies where risk management initiatives may be required.