

# **Periodic Benefit Risk Evaluation Report [PBRER]**

A Periodic Benefit Risk Evaluation Report is a format of safety report described by the ICH-E2C(R2) guideline which is used as a basis for the EU Periodic Safety Update Report (PSUR). The report 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 risk to regulatory authorities and identifies where risk management initiatives may be required.