

KEY COMMITTEES: BAYER DRUG SAFETY

Global Safety Committee:

Within Bayer's system of Medical Governance, the Global Safety Committee establishes and formalizes company positions on safety and medical questions; responds to regulatory requests involving drug safety and risk management activities and undertakes review and prepares approval of critical decisions such as those to seek regulatory review and approval of new compounds or indications. The Global Safety Committee also will decide on appropriate monitoring and reporting procedures to be used for pharmacoepidemiology studies of Bayer's Pharma Business products relating to potential human safety or efficacy issues.

Global Labeling Committee:

Responsible for ensuring the development, maintenance, distribution and use of consistent, up to date and harmonized labeling documents for all development and marketed products within the Bayer Group, the Global Labeling Committee reviews and approves all drug labels, reviews and approves changes or deviations from approved labels, and establishes and maintains Core Company Data Sheets (CCDS).

Protocol Review Committee

Responsible for evaluation and approval of the protocols for any clinical study sponsored or commissioned by Bayer's Pharma Business, the Protocol Review Committee's oversight will explicitly extend to company-sponsored or co-development studies in six categories including pharmacoepidemiological studies such as the i3 Drug Safety Study.

Critical Action Committee

Responsible for making recommendations to the Board of Management of Bayer's Pharma Business and/or the Bayer AG Board of Management regarding critical safety or quality issues with potential to adversely affect the company's commitment to safeguard patient health, the Critical Action Committee takes measures to minimize risk to humans and enhance the safe use of Bayer's marketed pharmaceutical products worldwide.