

Adverse reaction

An adverse reaction, is any adverse event or experience related to a medicine for which at least a reasonable causal relationship with the medicine's use is suspected. This is synonymous with adverse drug reaction (ADR), Suspected adverse (drug) reaction, Adverse effect, Undesirable effect.

Adverse reactions may arise from use of the medicine within or outside the terms of the marketing authorisation or from occupational exposure. Use outside the marketing authorisation includes off- label use, overdose, misuse, abuse and medication errors