A lack of confidence in the conclusions of an HTA owing to limitations in the available evidence.

Note 1: Uncertainty can take several forms, including: clinical uncertainty through missing data and the <u>external validity</u> of the trial design and population; parameter and structural uncertainty in the economic modelling; and affordability uncertainty in the financial impact estimates.

Note 2: To aid decision making, uncertainty can be characterized and reduced through the generation of additional evidence. In some situations, the uncertainty may be unresolvable. The financial risk associated with uncertainty can be mitigated using "risk share agreements".