Potential risk

An unexpected event for which there is suspicion of an association with a medicinal product, but where this association has not been confirmed. Some examples are:

- toxicological findings seen in non-clinical safety studies which have not been observed in clinical studies;
- adverse events observed in clinical trials or epidemiological studies for which the difference compared with the control group raises a suspicion of an association, but is not large enough to suggest a causal relationship;
- a signal arising from a spontaneous adverse reaction reporting system;
- an event associated with other active substances within the same class or which could be expected to occur based on the similar properties of the medicinal product.