Annex 1
of Pharmacovigilance Procedure
(subitem 1 of item 3 of section II)

Classification of adverse events following immunization (AEFI)/tuberculin diagnostics

Type of AEFI	Definition
Vaccine, tuberculin properties-related reaction	An AEFI/tuberculin diagnostics that is caused by effect of active components and/or adjuvants in composition of vaccine, tuberculin
Vaccine, tuberculin manufacturing failure - related reaction	An AEFI that is caused by effect of vaccine, tuberculin that is due to one or more manufacturing failures, including administration device provided by the manufacturer.
Immunization, tuberculin diagnostics programme error-related reaction	An AEFI that is caused by inappropriate vaccine, tuberculin handling, prescribing or administration and thus by its nature is preventable.
Immunization, tuberculin diagnostics anxiety-related reaction	An AEFI arising from psychological stress at immunization, tuberculin diagnostics.
Coincidental event	An AEFI that is caused by other factor than the above mentioned, but a temporal association with immunization, tuberculin diagnostics exists.