BOX 1. RAM system of the National Pharmacovigilance Network: definitions of adverse reaction and serious adverse drug reaction (ADR).

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| By adverse reaction it is intended a harmful and unintended effect consequent not only to the authorized use of a drug under normal conditions of use, but also to therapeutic errors and uses not complying with authorized indications, including misuse and abuse of the drug. |
| Serious adverse reactions include:   1. a fatal reaction; 2. a reaction that caused or prolonged hospitalization; 3. a reaction that has endangered the patient's life; 4. a reaction that has caused serious and permanent disability; 5. a reaction that caused congenital anomalies and/or birth defects; 6. a reaction that is included in the European list of Important Medical Events (IME) |
| The health worker can however define a serious reaction even if the conditions described above are not present, based on the relevance of the event.  All other situations (not included among those listed) are to be considered as not serious. |
| Source: Italian Drug Agency; http://www.agenziafarmaco.gov.it/content/online-i-dati-sulle-segnalazioni-di-sospette-reazioni-avverse-registrate-nella-rete-nazional |