

PHARMACOVIGILANCE GLOSSARY

A glossary of terms covering topics including adverse reactions and pharmacovigilance

Adverse event (AE); synonym: Adverse experience

Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not it is considered related to the medicinal product.

Adverse reaction; synonyms: Adverse drug reaction (ADR), Suspected adverse (drug) reaction

A response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include overdose, misuse, abuse and medication errors.

Consumer

A person who is not a healthcare professional – such as a patient, lawyer, friend or relative/parent/child of a patient.

Healthcare professional

For the purposes of reporting suspected adverse reactions, healthcare professionals are defined as medically qualified persons, such as physicians, dentists, pharmacists, nurses and coroners.

Medication error

Any unintentional error in the prescribing, dispensing, or administration of a medicinal product while in the control of the healthcare professional, patient or consumer.

Name of the medicinal product

The name which may be either an invented name not liable to cause confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.

The common name is the international non-proprietary name (INN) recommended by the World Health Organization, or, if one does not exist, the usual common name.

The complete name of the medicinal product is the name of the medicinal product followed by the strength and pharmaceutical form e.g. Elaprase 2 mg/ml concentrate for solution for infusion.

Pharmacovigilance

Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

In line with this general definition, underlying objectives of the applicable EU legislation for pharmacovigilance are:

- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and
- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public

Therefore, Pharmacovigilance is an activity contributing to the protection of patients' and public health.

Serious adverse reaction

Serious adverse reaction means an adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

Life-threatening in this context refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.

Medical and scientific judgement should be exercised in deciding whether other situations should be considered serious reactions, such as important medical events that might not be immediately life threatening or result in death or hospitalisation, but might jeopardise the patient or might require intervention to prevent one of the other outcomes listed above. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalisation, or the development of dependency or abuse.

Any suspected transmission via a medicinal product of an infectious agent is also considered a serious adverse reaction.

Spontaneous report, synonym: Spontaneous notification

An unsolicited communication by a healthcare professional or consumer to a company, regulatory authority or other organisation (e.g. the World Health Organization, a regional centre, a poison control centre) that describes one or more adverse reactions in a patient who was given one or more medicinal products and that does not derive from a study or any organised data collection scheme.

Stimulated reporting can occur in certain situations, such as direct healthcare professional communication (DHPC), a publication in the press or questioning of healthcare professionals by company representatives, and adverse reaction reports arising from these situations are considered spontaneous reports, provided the report meets the definition above.