Guideline on good pharmacovigilance practices (GVP)
P I: Vaccines for prophylaxis against infectious diseases – Definitions for inclusion in GVP Annex I Rev 2

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Comments should be provided using this [template](#). The completed comments form should be sent to gvp@ema.europa.eu.

**Note:** The final definitions will be included in GVP Annex I Rev 2.
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Adverse event following immunisation (AEFI)

See Vaccine pharmacovigilance, Vaccine product-related reaction, Vaccine quality defect-related reaction, Immunisation error-related reaction, Immunisation anxiety-related reaction

Failure to vaccinate

An indicated vaccine was not administered appropriately for any reason (see CIOMS-WHO\(^1\)). For interpreting what is appropriate, consider the explanatory note for Immunisation error-related reaction. See also Vaccination failure

Immunisation

The process of making a person immune.

For the context of Considerations P.I, immunisation refers to the process of making a person immune to an infection. See also Vaccination

Immunisation anxiety-related reaction

An adverse event following immunisation arising from anxiety about the immunisation (see CIOMS-WHO\(^2\)). In this definition immunisation means the usage (handling, prescribing and administration) of a vaccine for the purpose of immunising individuals (see CIOMS-WHO\(^3\)), which in the EU is preferably referred to as vaccination (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably\(^4\)). See also Adverse reaction, Vaccine pharmacovigilance, Vaccination

Immunisation error-related reaction

An adverse event following immunisation that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable (see CIOMS-WHO\(^3\)). In this definition immunisation means the usage (handling, prescribing and administration) of a vaccine for the purpose of immunising individuals (see CIOMS-WHO\(^5\)), which in the EU is preferably referred to as vaccination (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably\(^6\)). Inappropriate refers to usage (handling, prescribing and administration) other than what is licensed and recommended in a given jurisdiction based on scientific evidence or expert recommendations (see CIOMS-WHO\(^7\)). See also Adverse reaction, Vaccine pharmacovigilance, Vaccination

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Target population (vaccine); synonym: Vaccine target population

Persons who might be vaccinated in accordance with the indication(s) and contraindications in the authorised product information and official recommendations for vaccinations.

Vaccination

The administration of a vaccine with the aim to produce immune response.

See also Immunisation

Vaccination failure

Vaccination failure due to actual vaccine failure or failure to vaccinate (see CIOMS-WHO⁴).

Vaccination failure may be defined based on clinical endpoints or immunological criteria, where correlates or surrogate markers for disease protection exist. Primary failure (e.g. lack of seroconversion or seroprotection) needs to be distinguished from secondary failure (waning immunity) (see CIOMS-WHO⁵).

See also Vaccine failure, Failure to vaccinate

Vaccine

See Immunological medicinal product (Note for readers: This definition is already included in GVP A I Rev 1.)

Vaccine failure

Confirmed or suspected vaccine failure.

Confirmed clinical vaccine failure

Occurrence of the specific vaccine-preventable disease in a person who is appropriately and fully vaccinated taking into account the incubation period and the normal delay for the protection to be acquired as a result of immunisation (see CIOMS-WHO⁵).

Suspected clinical vaccine failure

Occurrence of disease in an appropriately and fully vaccinated person, but the disease is not confirmed to be the specific vaccine-preventable disease, e.g. disease of unknown serotype in a fully vaccinated person (based on CIOMS-WHO⁵).

Confirmed immunological vaccine failure

Failure of the vaccinated person to develop the accepted marker of protective immune response after being fully and appropriately vaccinated, as demonstrated by having tested or examined the vaccinated person at an appropriate time interval after completion of immunisation (based on CIOMS-WHO⁵).

Suspected immunological vaccine failure

Failure of the vaccinated person to develop the accepted marker of protective immune response after being fully and appropriately vaccinated, but with the testing or examination of the vaccinated person done at an inappropriate time interval after completion of immunisation (based on CIOMS-WHO⁵).

For interpreting what means appropriately vaccinated, consider the explanatory note for Immunisation error-related reaction.

See also Vaccination failure

Vaccine pharmacovigilance

The science and activities relating to the detection, assessment, understanding and communication of adverse events following immunisation and other vaccine- or immunisation-related issues, and to the prevention of untoward effects of the vaccine or immunisation (see CIOMS-WHO\(^6\)).

In this definition, immunisation means the usage of a vaccine for the purpose of immunising individuals (see CIOMS-WHO\(^7\)), which in the EU is preferably referred to as vaccination (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably\(^8\)). Usage includes all processes that occur after a vaccine product has left the manufacturing/packaging site, i.e. handling, prescribing and administration of the vaccine (see CIOMS-WHO\(^9\)).

An adverse event following immunisation (AEFI) is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. While this AEFI definition is compatible with the definition of adverse event applied in the EU, the AEFI definition is not needed to describe pharmacovigilance for vaccines in the EU. However, EU guidance on pharmacovigilance for vaccines makes use of the terminology suggested by CIOMS-WHO\(^7\) regarding possible causes of adverse events, turning them into suspected adverse reactions. A coincidental event is an AEFI that is caused by something other than the vaccine product, immunisation error or immunisation anxiety (see CIOMS-WHO\(^9\)).

See also Adverse event, Immunisation anxiety-related reaction, Immunisation error-related reaction, Vaccine product-related reaction, Vaccine quality defect-related reaction, Vaccination

Vaccine product-related reaction

An adverse event following immunisation that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product (see CIOMS-WHO\(^7\)).

In this definition immunisation means the usage (handling, prescribing and administration) of a vaccine for the purpose of immunising individuals (see CIOMS-WHO\(^7\)), which in the EU is preferably referred to as vaccination (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably\(^8\)).

See also Adverse reaction, Vaccine pharmacovigilance

Vaccine quality defect-related reaction

An adverse event following immunisation that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product including its administration device as provided by the manufacturer (see CIOMS-WHO\(^8\)).

In this definition immunisation means the usage (handling, prescribing and administration) of a vaccine for the purpose of immunising individuals (see CIOMS-WHO\(^7\)), which in the EU is preferably referred to as vaccination

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(in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination are used interchangeably).

For the purpose of this definition, a vaccine quality defect is defined as any deviation of the vaccine product as manufactured from its set quality specifications (see CIOMS-WHO).

See also Adverse reaction, Vaccine pharmacovigilance