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

Preparation and adoption of draft	See Timetable for P.I
Public consultation, finalisation and date for coming into effect	idem

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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.

See websites for contact details

European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu

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10 **Table of contents**

11 Adverse event following immunisation (AEFI)3

12 Failure to vaccinate3

13 Immunisation3

14 Immunisation anxiety-related reaction3

15 Immunisation error-related reaction3

16 Target population (vaccine); synonym: Vaccine target population4

17 Vaccination4

18 Vaccination failure4

19 Vaccine4

20 Vaccine failure4

21 Vaccine pharmacovigilance5

22 Vaccine product-related reaction5

23 Vaccine quality defect-related reaction5

24

25

26 **Adverse event following immunisation (AEFI)**

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

29 **Failure to vaccinate**

30 An indicated vaccine was not administered appropriately for any reason (see CIOMS-WHO¹).

31 For interpreting what is appropriate, consider the explanatory note for Immunisation error-related reaction.

32 *See also Vaccination failure*

33 **Immunisation**

34 The process of making a person immune.

35 For the context of Considerations P.I, immunisation refers to the process of making a person immune to an
36 infection.

37 *See also Vaccination*

38 **Immunisation anxiety-related reaction**

39 An adverse event following immunisation arising from anxiety about the immunisation (see CIOMS-
40 WHO²).

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

45 *See also Adverse reaction, Vaccine pharmacovigilance, Vaccination*

46 **Immunisation error-related reaction**

47 An adverse event following immunisation that is caused by inappropriate vaccine handling, prescribing
48 or administration and thus by its nature is preventable (see CIOMS-WHO³).

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

53 Inappropriate refers to usage (handling, prescribing and administration) other than what is licensed and
54 recommended in a given jurisdiction based on scientific evidence or expert recommendations (see CIOMS-
55 WHO^{footnote nr}).

56 *See also Adverse reaction, Vaccine pharmacovigilance, Vaccination*

¹ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

² Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

³ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

57 **Target population (vaccine); synonym: Vaccine target population**

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

60 **Vaccination**

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

62 *See also Immunisation*

63 **Vaccination failure**

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

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

68 *See also Vaccine failure, Failure to vaccinate*

69 **Vaccine**

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

71 **Vaccine failure**

72 Confirmed or suspected vaccine failure.

73 Confirmed clinical vaccine failure

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

77 Suspected clinical vaccine failure

78 Occurrence of disease in an appropriately and fully vaccinated person, but the disease is not confirmed
79 to be the specific vaccine-preventable disease, e.g. disease of unknown serotype in a fully vaccinated
80 person (based on CIOMS-WHO^{footnote nr}).

81 Confirmed immunological vaccine failure

82 Failure of the vaccinated person to develop the accepted marker of protective immune response after
83 being fully and appropriately vaccinated, as demonstrated by having tested or examined the
84 vaccinated person at an appropriate time interval after completion of immunisation (based on CIOMS-
85 WHO^{footnote nr}).

86 Suspected immunological vaccine failure

87 Failure of the vaccinated person to develop the accepted marker of protective immune response after
88 being fully and appropriately vaccinated, but with the testing or examination of the vaccinated person
89 done at an inappropriate time interval after completion of immunisation (based on CIOMS-WHO^{footnote nr}).

⁴ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

⁵ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

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

92
93 *See also Vaccination failure*

94 **Vaccine pharmacovigilance**

95 The science and activities relating to the detection, assessment, understanding and communication of
96 adverse events following immunisation and other vaccine- or immunisation-related issues, and to the
97 prevention of untoward effects of the vaccine or immunisation (see CIOMS-WHO⁶).

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

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

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

113 **Vaccine product-related reaction**

114 An adverse event following immunisation that is caused or precipitated by a vaccine due to one or
115 more of the inherent properties of the vaccine product (see CIOMS-WHO⁷).

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

120 *See also Adverse reaction, Vaccine pharmacovigilance*

121 **Vaccine quality defect-related reaction**

122 An adverse event following immunisation that is caused or precipitated by a vaccine that is due to one
123 or more quality defects of the vaccine product including its administration device as provided by the
124 manufacturer (see CIOMS-WHO⁸).

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

⁶ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

⁷ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

⁸ Council for International Organizations of Medical Sciences (CIOMS). Definition and application of terms of vaccine pharmacovigilance (report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance). Genève: CIOMS; 2012.

127 (in the report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance the terms immunisation and vaccination
128 are used interchangeably^{footnote nr}).

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

131 *See also Adverse reaction, Vaccine pharmacovigilance*

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