

Vaccine Pharmacovigilance Definition

Preamble

The Terms of Reference for the CIOMS/WHO Working Group on Vaccine Pharmacovigilance included the development of standardized definitions relevant to the monitoring of the safety of vaccines during clinical trials and for the purposes of vaccine pharmacovigilance in the post-authorization period. The Vaccine Pharmacovigilance definition was initially formulated at the first meeting of the Working Group in November 2005, and finalized at the fifth meeting in October 2007.

Definition

Vaccine pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, prevention, and communication of adverse events following immunization, or of any other vaccine- or immunization-related issues.

Explanatory Notes and Comment

The goal of vaccine pharmacovigilance is the early detection of and appropriate and timely response to adverse events following immunization in order to minimize negative effects to the health of individuals and lessen the potential negative impact on immunization of the population. Continuous risk-benefit assessment and risk management are integral to the vaccine pharmacovigilance process.

There is a very high level of safety required for vaccines. Elements to consider when conducting vaccine pharmacovigilance include the following:

- Vaccines are usually administered to healthy people, including infants.
- Vaccines may be administered to the vast majority of the population or of a birth cohort or to groups at high risk for disease complications.
- Subpopulations may be more susceptible to experience certain adverse events following immunization.
- The age at the time of immunization may coincide with the emergence of certain age-related diseases (e.g., neurodevelopmental disorders).
- Immunization with certain vaccines is mandated in some countries.
- The benefits of immunization may not be immediately visible, particularly if the target disease incidence is low.
- Due to the low acceptance of risks, intensive investigation of serious adverse events following immunization, even if rare, is necessary.
- Non-serious adverse events following immunization also should be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization, or have an impact on the acceptability of immunization in general.
- Appropriate methods are needed to detect and assess any potential causal association of serious, rare, and/or delayed adverse events, or of adverse events in subgroups, with immunization.

- Consideration of dechallenge and rechallenge differs for vaccines compared with other medicinal products. Vaccines are frequently administered only once or with long intervals, and serious adverse events following immunization often prevent further vaccine administration. Dechallenge may not be applicable to vaccines, given their long-term immunological effects, and rechallenge information is only rarely available.
- Vaccines are often administered concomitantly with other vaccines, making causal attribution to a specific vaccine difficult.
- The administration of live vaccines can lead to disease caused by the attenuated organisms in vaccinees or their contacts; this should be differentiated from coinciding natural infection.
- Vaccines are complex biological products, which may include multiple antigens, live organisms, adjuvants, and preservatives. Each component may have unique safety implications. Variability and (even small) changes in the manufacturing process may have impact on quality, protective effect, and safety. Batch information is of crucial importance.
- New vaccines are increasingly based on new production and administration technologies, with new adjuvants and alternative routes of administration, necessitating adapted safety monitoring systems.
- Depending on the mode and extent of use of a vaccine, it may elicit a degree of herd immunity to a specific disease. When assessing the risk-benefit of a vaccine, herd immunity effects as well as individual protection need to be taken into account.
- Effective communication regarding the safety of vaccines and immunization is challenging. Despite strong evidence that a serious adverse event is not related to immunization, perceptions of harm may persist and may potentially have a negative impact on immunization of the population.