The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949 to serve the scientific interests of the international biomedical community.

The Council for the International Organizations of Medical Sciences (CIOMS) and WHO established a joint working group on vaccine pharmacovigilance in 2005, recognizing that vaccines represent a special group of medicinal products with issues specific to the monitoring and assessment of vaccine safety.

- To propose standardized definitions relevant to the monitoring of safety of vaccines intended for the prevention of infectious diseases during clinical trials and for the purposes of vaccine pharmacovigilance after licensing,
- To contribute to the development, review, evaluation and approval of AEFI case definitions as developed by the Brighton Collaboration process, and to contribute to their dissemination, including their translation into additional languages,
- To collaborate with other CIOMS Working Groups, especially that on Standardized MedDRA Queries (MedDRA is the Medical Dictionary for Regulatory Activities) and the CIOMS Working Group VIII on Signal Detection on issues relevant to vaccine safety.

The purpose of developing standardized definitions and terminology, or other guidance documents relevant to vaccine safety, is to contribute to the harmonization of vaccine pharmacovigilance among different stakeholder groups and bodies. The principal stakeholders are represented among the 22 Joint Working Group members from the vaccine industry, regulatory agencies, national and international public health agencies (including WHO and CIOMS) and academia. A number of subgroups have also
been established to carry out specific assigned work.

Additional activities that the CIOMS/WHO Working Group on Vaccine Pharmacovigilance has engaged in, although not formally incorporated in its terms of reference, have included providing consultations and expert inputs to other vaccine pharmacovigilance initiatives, such as the Global Vaccine Safety Blueprint project led by WHO (discussed later in this module), and the development of a vaccine dictionary by the Uppsala Monitoring Centre.

*Uppsala Monitoring Centre (UMC)* An independent centre which receives adverse drug reactions from national pharmacovigilance centres in WHO member countries and generates signals of possible side-effects.