WORLD HEALTH ORGANIZATION (WHO) POSITION STATEMENT SAFETY AND PRE-QUALIFICATION OF ORAL POLIO VACCINE (OPV)

May 2006

Background

The following statement affirms the quality and safety of OPV, which is continuously monitored by WHO. The vaccine procured by UN agencies for the Global Polio Eradication Initiative is of the same high quality world-wide.

Guaranteeing the safety and quality of OPV

All vaccines, including OPV, that are procured by UN agencies such as WHO and UNICEF must meet specifications set by the Expert Committee on Biological Standardisation (ECBS).[1] These specifications govern the exact contents used in the production of OPV and ensure that the purity of the vaccine meets all technical criteria. The ECBS specifications make it impossible for OPV to contain any other undeclared biologically active substances, such as other viruses (including HIV), steroid hormones or other materials.

To ensure that vaccines procured by UN agencies meet these specifications, WHO verifies compliance with good manufacturing practices (GMP) and ensures a system of quality assurance and strict controls is in place. These mechanisms, known as WHO 'pre-qualification' of vaccines, are designed to guarantee that the manufacture of OPV used in the Global Polio Eradication Initiative meets international ECBS specifications.

OPV used for mass vaccination campaigns

The Global Polio Eradication Initiative partnership procures only WHO pre-qualified OPV for national immunization programmes and mass immunization campaigns. All UN-procured OPV for polio eradication campaigns comes from manufacturers who have been pre-qualified by WHO.

The WHO pre-qualification process systematically ensures that all UN-procured vaccines are safe, potent and of high purity standards. Only WHO pre-qualified OPV, that has been satisfactorily assessed for compliance with technical specifications and the above-mentioned requirements, can be considered in international tenders by UNICEF. Each batch of OPV undergoes full testing by the manufacturer, and the test results are reviewed by the National Regulatory Authority for biological substances (NRA) of the country where the OPV is produced, prior to its release. In addition, the NRA conducts a battery of tests on randomly selected batches.

The pre-qualification assessment procedure established by WHO requires a fully functional National Regulatory Authority (NRA) in the country of manufacture. The NRA performs the control and release of each batch of OPV, ensures a detailed review of production process and quality control methods, and verifies production

[1] As described in the WHO Technical Report Series 904, adopted by the Expert Committee on Biological Standardization in 2002, which outlines the procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies (WHO/V&B/02.08).

consistency. These procedures are further supported through random testing of vaccines by WHO-contracted laboratories which ensure compliance with WHO requirements and tender specifications on a continuing basis. WHO also monitors and responds to vaccine-related complaints from the field on an ongoing basis.

Experience with safety and effectiveness of pre-qualified OPV

The safety and effectiveness of WHO pre-qualified OPV has been reaffirmed by the more than 15 years of experience of the Global Polio Eradication Initiative.

OPV was developed in the 1950s and was approved for use 40 years ago. Since 1988, over 10 billion doses of pre-qualified OPV have been administered to children world-wide during mass immunization campaigns, as part of the global effort to eradicate polio. These campaigns have reduced the number of polio cases worldwide since1988 by 99%. The number of polio endemic countries has been reduced from more than 125 in 1988 to just four at the beginning of 2006.