First Vaccine from China to be pre-qualified by WHO

A newly accessible vaccine against **Japanese Encephalitis** (JE) is going to make the protection of more children in developing countries easier. The vaccine, manufactured in China, only needs to be given in **one dose**, it can be used for infants, and it is less expensive than other JE vaccines.

Today, the World Health Organization (WHO) has added the vaccine to its list of "pre-qualified" medicines, meaning that WHO has given the vaccine its stamp of approval in safety and efficacy terms, and United Nations procuring agencies can now source this vaccine. This is the first Chinese-produced vaccine to be prequalified by WHO.

"This is a welcome development both in the fight to protect children in developing countries from JE and in the future availability of vaccines more generally, as China is now producing vaccines up to WHO standards," says WHO Director-General Dr Margaret Chan. "There is a huge potential for vaccine manufacture in China and we hope to see more and more Chinese vaccines become WHO prequalified. The whole world will benefit."

Japanese encephalitis, a mosquito-borne flavivirus infection is a severe disease that involves inflammation of the brain. It is major public health problem and is endemic with seasonal distribution in parts of China, the Russian Federation's south-east, and South and South-East Asia. As there is no specific treatment for Japanese encephalitis, supportive care in a medical facility is important to reduce the risk of death or disability. The disease is preventable by proven effective vaccines.

The newly accessible vaccine is available to the world now thanks to the outcome of several years of collaboration between WHO and the authorities of China on vaccine production standards and regulation.

In March 2011, WHO announced that the national drug regulatory authority of China, the State Food and Drug Administration (SFDA), and affiliated institutions, had met WHO indicators for a functional vaccine regulatory system. Herewith vaccine manufacturers in China became eligible to apply for WHO prequalification of vaccines, as long as their vaccines met WHO quality and safety standards.

The vaccine prequalification procedure is a service provided by WHO which guarantees that individual vaccines meet international standards of quality, safety and efficacy and are appropriate for the target population. United Nations procurement agencies can only purchase vaccines that have "passed" the rigorous review process involved.

It is expected that other Chinese manufacturers will soon follow suit and apply for pre-qualification of their vaccines. This is expected to have a significant, beneficial impact on global supply of vaccines of assured quality.

The close collaboration between PATH and the vaccine manufacturer over the years led to the successful prequalification of the JE vaccine. In addition, the Bill & Melinda Gates Foundation also provided support through a grant to PATH. At the upcoming GAVI Alliance Board meeting, which will be held in Cambodia in November 2013, the GAVI Alliance will consider opening a window for financial support for JE vaccine. If the Board approves this, eligible countries would be able to apply for GAVI support from 2014, with UNICEF leading the international procurement efforts for the vaccine.