

Frequently Asked Questions (FAQs)

Quinvaxem vaccine

Q. What is Quinvaxem vaccine?

A. Quinvaxem is a 'pentavalent' vaccine that protects children against 5 killer diseases: diphtheria, tetanus, pertussis, *Haemophilus Influenza* type B and hepatitis B.

Since it was prequalified by WHO in 2006, 400 million doses of Quinvaxem have been administered in 91 countries. The vaccine has a very good safety record.

The vaccine was included in Viet Nam's National Expanded Immunization Programme in June 2010 under the approval of the Government. Since its introduction, Viet Nam has administered 15.2 million doses of Quinvaxem across the country.

Q. So why are people talking about it now?

A. Between December 2012 and March 2013 nine deaths were reported in Viet Nam shortly after the child had received a pentavalent vaccine.

As a precautionary measure, Viet Nam decided to suspend the use of the pentavalent vaccine. However, after a thorough review of the cases, no link with vaccination could be identified and the Government has since lifted the ban on its use.

As a small number of serious Adverse Events Following Immunization (AEFI) have also been reported from Sri Lanka, Pakistan, and Bhutan following administration of pentavalent vaccines a global independent expert panel was asked to review the safety of the vaccine.

This review took place in June 2013 and concluded that no unusual reaction could be attributed to pentavalent vaccines.

It is important to realize that when millions of children are vaccinated a very small number of adverse events may occur following immunization. Any incident involving the safety of even a single child is a major concern, yet the risks of not vaccinating a child are much higher.

Q. Is the global level expert review report available?

A. Yes the report is publicly available. The full report of the Global Advisory Committee on Vaccine Safety (GACVS) is available here http://www.who.int/vaccine_safety/committee/topics/pentavalent_vaccine/Jul_2013/en/index.html

Q. It has been reported that the deaths following vaccination in Vietnam are very similar to each other, and similar to those reported in other countries. Is that true?

A. No. The independent investigation noted that the cases did not follow a similar pattern. In many instances, an alternative cause of death was identified, such as an on-going infection or a congenital malformation

Q. Is Quinvaxem safe?

A. Yes. There are strict quality controls at every step of the manufacturing and supply processes. Quinvaxem is prequalified by WHO, to guarantee that the vaccine is of assured quality according to the highest global standards.

Q. Are there any problems with this vaccine in particular?

A. No. WHO is not aware of any quality issue with the vaccines supplied to Viet Nam. All GAVI supported vaccines procured through UNICEF Supply Division are prequalified by WHO which implies they are of assured quality. This process is in addition to the work of the country of production's National Regulatory Authority (NRA) and involves a review of the product's clinical data, production process, and manufacturing facilities. WHO also visits the production sites, and tests samples on top of the testing requirements for sample batches produced.

Q. Are there any side effects?

A. Like all vaccines, Quinvaxem can have some mild side effects. They include low grade fever, localized swelling and general short term discomfort.

In a very rare number of cases – less than one per million – a child can have a severe allergic reaction to the vaccine. Health care providers are trained to respond and if prompt medical treatment is given the child can make a full recovery.

Q. What is the role of the WHO or UNICEF in administrating the vaccine in developing countries?

A. WHO and UNICEF provide technical assistance to local authorities. The agencies do not administer the vaccines directly but provide support with training, supervision and monitoring processes to ensure quality.

Q. As a major supplier of vaccines, how do UNICEF and WHO ensure the safety of vaccines?

A. UNICEF only buys vaccines that have been pre-qualified by WHO and meet established international standards. UNICEF Supply Division then ensures that GAVI-procured vaccines are delivered to national storage facilities.

WHO follows a rigorous procedure to evaluate vaccine production facilities and quality standards. These evaluation procedures ensure that good manufacturing practices are adhered to and that national regulatory authorities are well equipped to consistently produce high quality products.

The quality of vaccines shipped to countries is regularly monitored through rounds of random

testing performed at six-month intervals by WHO. In addition, a full re-evaluation of all pre-qualified vaccines takes place every two years.

Q. UNICEF currently buys vaccines from developing countries such as India and Indonesia. Are these vaccines as safe as those produced in developed countries?

A. UNICEF buys vaccines from qualified producers in both industrialized and developing countries. All vaccine manufacturers meet international standards set by WHO. UNICEF has been buying vaccines for more than 35 years and has been procuring vaccines from WHO qualified producers in developing countries for more than fifteen years.

Q. Can countries procuring vaccines through UNICEF decide on the vaccine supplier they prefer?

A. No. UNICEF procures vaccines from several WHO pre-qualified manufacturers. Vaccines are procured according to the producers' abilities to meet quality standards and defined delivery schedules. This approach ensures an efficient global supply system for vaccines.

Q. Can countries safely use different brands and sources of the same types of vaccines? In other words, are different brands of the same types of vaccines safely interchangeable?

A. Different brands or sources of the same types of vaccines can be used interchangeably if they are all procured from WHO pre-qualified producers.

Q. Why does UNICEF send vaccines manufactured in developing countries (e.g. India/Indonesia) to some countries while others receive vaccines from European or American manufacturers?

A. Decisions regarding the source of a particular shipment of vaccine depend mainly on which manufacturer has the required quantity at the time it is needed. All UNICEF procured vaccines go through a strict WHO quality control procedure, irrespective of where they are manufactured.

For more information please visit these suggested links:

<http://www.who.int/topics/immunization/en/>

<http://www.wpro.who.int/topics/immunization/en/>

<http://www.wpro.who.int/vietnam/topics/immunization/factsheet/vi/index.html>

<http://www.unicef.org/immunization/>

<http://www.gavialliance.org/country/vietnam/>

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