
Joint WHO-UNICEF Statement 2
26 April 2010

**WHO RECOMMENDS
RECALL AND DESTRUCTION OF ALL LOTS OF SHAN5 VACCINE
AS A PRECAUTIONARY MEASURE**

The World Health Organization (WHO) recommends as a precautionary measure the recall and destruction of all lots of the Shantha Biotechnics (India) produced pentavalent Shan5 (DTwP-hepatitis B-Hib) vaccine remaining in stock in countries.

The Shan5 vaccine currently held in stock in countries should not be used. Countries have already identified the concerned stock and are now requested to organize transport of all unused vaccine to central level, in coordination with WHO and UNICEF country offices (or the in-country entity facilitating the procurement of the vaccines if vaccines were not supplied through UNICEF or the Pan American Health Organization). Once collected, the vaccine will be handed over to the named Shantha representative in the country for appropriate handling of return and/or destruction.

This recommendation is based on the advice of an ad hoc committee of experts convened on 8 April, following incidents of white sediment sticking to Shan 5 vaccine vials that was difficult or impossible to resuspend. There have been no reports of any side effects from the use of Shan5.

WHO recommends that countries continue vaccination using pentavalent vaccine from an alternative manufacturer or an alternative DTP-containing vaccine. Countries should contact WHO or UNICEF country offices (or the in-country entity facilitating the shipments or procurement of these vaccines) for assistance with ensuring sufficient supply of vaccine for continuation of immunization programmes.

Further advice and support on the necessary process for collection, return and destruction of the vaccine will be provided to the concerned UNICEF/WHO country offices. Countries supplied through other channels should coordinate directly with a Shantha Biotechnics representative.

Background

- During recent months, WHO received vaccine quality complaints from Colombia, Comoros, and Nepal regarding the presence of a white sediment sticking to glass vials containing Shan5 vaccine which would not re-suspend even after vigorous shaking.
- On 19 February, WHO recommended the temporary suspension of the distribution and use of specific lots of Shan5 vaccine as a precautionary measure pending investigation.

- On 12 March, WHO recommended that the procurement and use of all lots of the Shan5 vaccine be temporarily suspended, after WHO received reports that additional lots, not included in the temporary suspension, showed a similar problem. Countries were advised to put any remaining vaccine into quarantine until further notice.
- The manufacturer was asked to provide additional data and WHO undertook independent testing in WHO-contracted laboratories.
- WHO called on an ad hoc committee of experts (from regulatory, vaccine manufacturing and immunization programme management fields) to review reports of the investigation from the manufacturer, results of WHO-commissioned tests, and the physical appearance of the Shan5 vaccine received from the countries. Samples of lots of the Shan5 vaccine received during the prequalification process and other DTP combination vaccines were also reviewed.
- The committee concluded that the batches of the product being held in quarantine are unsuitable for use and should be destroyed. This recommendation was based on several factors: the product has a different physical appearance to that which was prequalified; there are uncertainties about the safety and immunogenicity profile of the vaccine in this situation (although no reports of adverse events following immunization have been received); and the root cause of the change in physical appearance has not been established.

Shan5 vaccine quality, safety and efficacy

Although no reports of adverse events following immunization have been received, in view of the changed physical appearance of the affected lots, there remain uncertainties about the safety and immunogenicity profile of the vaccine. While the difficulty in resuspending the vaccine suggests that the full dose would not be given when using affected vials, a change in efficacy has not yet been proven..

Given this, WHO does not recommend revaccination of individuals who have received the full DTP-hepatitis B-Hib vaccination schedule using Shan5 at present. For individuals who have begun, but not completed, the schedule using Shan5, an alternative vaccine or vaccines should be used to complete the schedule.

Samples from affected vaccine lots are being tested in WHO-contracted laboratories, to check for a change in immunogenicity. Based on the results of these tests WHO will review its current advice not to revaccinate children who have received the full primary series with Shan 5. No other vaccine quality complaints besides the flocculation described above have been reported to WHO.

Shan5 vaccine composition and WHO prequalification

Shan5 is a combined, pentavalent vaccine containing diphtheria and tetanus toxoids, whole cell pertussis, recombinant DNA derived hepatitis B surface antigen, and components of *Haemophilus influenzae* type b (Hib). The vaccine is absorbed onto aluminium salts as an adjuvant and preserved with thiomersal.

Shan5 remains on the list of WHO prequalified vaccines for the time being. If, however, the manufacturer is not able to identify the root cause of the quality issue and prepare a robust plan for corrective action within a period of two months, the product will be removed from the list of WHO prequalified products. The list of prequalified vaccines on the WHO web site currently indicates that WHO recommends recall and destruction of remaining stocks as a precautionary measure.

Shan5 and alternative vaccine supply

According to updated estimates, between November 2008 and February 2010, almost 24 million doses of this vaccine were supplied to countries through UNICEF and the Pan American Health Organization (PAHO) Revolving Fund. The vaccine is also procured directly by a number of countries.

UNICEF and PAHO have been working with alternative suppliers of pentavalent vaccines and with the concerned countries to ensure that there is an adequate alternative supply of vaccines for continuation of immunization programmes.