

Interim Annual Progress Report

GAVI Yellow Fever Vaccine Stockpile

July 2004

1. Background

At its Dakar meeting on the 18-19th November 2002, the GAVI Board approved the establishment of a yellow fever (YF) vaccine stockpile to be loaned for outbreak response and used for preventive campaigns. The approval was for 6 million doses each year for an initial period of 3 years. In order to clearly outline the procedures for the establishment, use and replenishment of the stockpile; a series of meetings and videoconferences were held with representatives from the Vaccine Fund, WHO and UNICEF Supply Division (SD) at the beginning of 2003. Consequently, the procedures were agreed upon and written in a document titled "*The Yellow Fever Vaccine Stockpile: Procedures for Establishment, Use and Replenishment of the Yellow Fever Vaccine Stockpile Supported by GAVI and the Vaccine Fund*" which also outlines the roles and responsibilities of each agency.

In summary, the document states the following operational procedures and responsibilities:

- The annual stockpile of 6 million doses will be accumulated by the manufacturer at the beginning of the year.
- In the event of a YF outbreak during the year, vaccine from the stockpile may be released and shipped to affected countries. WHO, as part of the YF sub-group of the International Coordinating Group for Provision of Meningococcal Vaccines (ICG) co-ordinates the assessment of country documentation and requests for emergency support. According to the ICG mandate, the use of the stockpile is prioritized for the countries that are not able to find either the vaccine or the funds to purchase it for a prompt outbreak response. If the outbreak is verified and these conditions are met, WHO requests from UNICEF SD to allocate YF vaccine from the stockpile.
- Vaccines used for this purpose are expected to be replenished before the end of the calendar year, so that the total amount of annual stockpile is available for use in preventive campaigns. The availability of replenished vaccine will depend on the time funding is received, the quantity to be replenished and the production plans of the manufacturers.
- At the beginning of the following year, all remaining vaccine in the stockpile will be released for shipment and used in preventive campaigns in the countries identified by WHO and UNICEF as being at high risk for yellow fever.
- As these planned campaigns will deplete the stock in hand, the following year's stockpile should be already accumulated and ready to be loaned for outbreak response.

The experience with the YF stockpile in 2003 and in the first half of 2004 is summarized in this report.

2. Accumulation of the stockpile

2003 stockpile: Once the procedures were agreed upon, the Vaccine Fund transferred the funds to the Vaccine Fund Trust Account at UNICEF in May 2003, and the process was initiated. The first 6 million doses were successfully accumulated by Aventis by the end of August 2003.

2004 stockpile: The 2004 stockpile was not accumulated by January 2004 as originally planned. It is expected to be available according to the following schedule given by the manufacturer:

- 2,000,000 doses by the end of May 2004
- 1,000,000 doses by the end of June 2004
- 3,000,000 doses by the end of July 2004

A number of factors contributed to this late accumulation including:

- The delay in the request to the Vaccine Fund for approval and transfer of funds in 2003, causing UNICEF SD to start negotiations with the manufacturer only at the end of October.
- Manufacturing problems in Aventis causing delays in vaccine production
- Unplanned vaccine demand from Aventis by several Latin American countries due to YF outbreaks at the end of 2003.

3. Utilization and replenishment of stockpile for outbreak response

2003 stockpile: After the stockpile was established in July/August 2003, a YF outbreak occurred in Sierra Leone in September 2003. A response campaign was started using an emergency vaccine stock existing in the country. In addition, 150,000 doses of YF vaccine from the stockpile were used to carry out the campaign as planned. Several contacts were made with potential donors by WHO at country and HQ level to replenish this vaccine, but no pledge was obtained. Consequently, the balance of stockpile was 5 850 000 doses at the end of 2003. The duration of the 2003 stockpile contract was extended from January 2004 to May 2004.

2004 stockpile: In January 2004, an outbreak in Colombia occurred and an emergency supply of 1,000,000 doses of vaccine from 2003 stockpile was shipped to the country to meet the immediate need. Another YF outbreak occurred in Liberia in February 2004, requiring 495,000 doses of vaccine from 2003 stockpile for the outbreak response. Because the 2004 stockpile was not yet accumulated, the scheduled shipment for one of the preventive campaigns had to be postponed in order to respond these outbreaks.

Regarding the replenishment of the vaccine used for Liberia outbreak, a fund-raising proposal was written and widely disseminated to potential donors by both WHO HQ and UNICEF. Two pledges from Ireland and Norway were received. Subsequently, UNICEF HQ transferred 150 000 USD for replenishment to Supply Division in May 2004. The Colombian government has not yet transferred the funds for the replenishment of 1 000 000 doses of vaccine.

4. Utilization of stockpile for preventive campaigns

2003 stockpile: Given the design of the stockpile, the first year was dedicated to planning and preparation activities for the preventive campaigns that would take place early next year, using the vaccine stock of 2003. WHO and UNICEF agreed on the prioritization criteria to select the countries to conduct preventive campaigns using vaccine from the stockpile:

1. Evidence that populations to be vaccinated are at high risk for YF – based on best available epidemiological, entomological and immunization coverage data.
2. The introduction of YF vaccine as part of routine infant immunization.
3. The implementation of case-based surveillance for yellow fever.
4. The ability to mobilize part or all funds needed for the operational costs of the preventive campaign.
5. The ability to implement a safe and effective preventive campaign.

As a result of the evaluation using these criteria, Senegal and Guinea were identified to implement preventive campaigns in 2004. Planning missions were carried out by WHO to both countries by the end of May 2003. Detailed micro plans were developed with the Ministry of Health where data on persons already vaccinated in the entire country was obtained, and the population targeted for vaccination in each high-risk district was calculated. The countries have been allocated 3,000,000 doses of YF vaccine each, from the stockpile. The microplans also included a detailed budget required for the campaign (excluding the cost of bundled vaccine). Partners in those countries were met and sensitized on the importance of the preventive campaigns in the control of yellow fever, and the need to mobilize funds for the operational costs of the campaigns.

2004 stockpile: As per the stockpile agreement, all remaining doses from 2003 were to be released to be used in preventive campaigns no later than during the first month of 2004. The delayed accumulation schedule in 2004 contributed to postpone the shipment of a part of previous year's stock for preventive campaigns, as otherwise there would be no vaccine in hand until June 2004 to be used in the event of a YF outbreak.

In January 2004, Senegal received 3 000 000 doses of bundled YF vaccine from the 2003 stockpile to use in the campaign. In the meantime, Ministry of Health has decided to extend the campaign to cover all the susceptible population in the country, and considered purchasing an additional 3 000 000 doses of vaccine. Following a government change in April, Senegal is currently waiting for the political decision to mobilize necessary funds for the campaign.

The vaccine for Guinea was divided into two shipments, in order to maintain a minimum supply in the stockpile in case of an outbreak. As mentioned earlier, delay in accumulation of 2004 stockpile has prevented Guinea to receive all vaccine at the beginning of the year. In May 2004, the country received 1 350 000 doses of bundled YF vaccine from the 2003 stockpile. Pending the replenishment from PAHO/Colombia, the remaining 1 650 000 doses are estimated to be dispatched by mid to end July 2004. The country is in the process of raising the operational costs needed for the campaign.

Currently WHO is in the process of identifying countries to conduct preventive campaigns in 2005.

ANNEX 1

DRAFT LETTER FROM GAVI EXECUTIVE SECRETARY TO VACCINE FUND

Mr Jacques-François Martin
President
The Vaccine Fund
36 Quai Fulchiron
69005 LYON

..... June 2004

Dear Jacques-François,

Request to approve allocation of funds for the third year (2005) of yellow fever vaccine stockpile

We would like to formally request Vaccine Fund approval for the allocation of US\$6,046,080 to purchase 6 million doses of yellow fever vaccine stockpile for the year 2005. The actual claim to release the transfer of funds to the Vaccine Fund Trust account at UNICEF will be made by Ms Marilena Viviani in UNICEF New York.

The cost of the 6 million doses in 20-dose vials is higher than the initial estimated cost made in May, 2002 of US\$3,000,000. This difference is mainly due to the increase in vaccine price, as the manufacturer will only supply YF vaccine in 10-dose vials in 2005 due to the upgrading of manufacturing facilities. Aventis has confirmed that the 2005 price of a 10-dose vial is 0.88 USD per dose, compared to the 2004 price of 0.45 per dose. Please note that in addition to the vaccine cost, the above amount includes the associated safe injection equipment and delivery costs.

It is also noted that the stockpile can only be arranged with Aventis at this time due to the fact that Aventis is the manufacturer that can handle properly a stockpile given the production size, warehouse capacity and capacity of response in emergency situations. No other manufacturers can offer these capabilities at this point in time.

An interim report on the use of the stockpile is attached for your information. Once the stockpile of 2003 has been depleted, a detailed report of its use will be provided to the GAVI Board at its December 2004 meeting.

We would be happy to provide you with further details on the use of the yellow fever vaccine stockpile upon your request.

Yours sincerely,

Dr Tore Godal
Executive Secretary
Encl.

cc: Members of the GAVI Board and Working Group
 Vaccine Fund Executive Committee
 Ms Alice Albright, Vaccine Fund
 Mr Terry Brown, Ms Marilena Viviani, UNICEF New York
 Mr Stephen Jarrett, Ms Shanelle Hall, UNICEF Supply Division
 Mr Umberto Cancellieri, GAVI Secretariat