No. T 22020/4/2002-CH Government of India Ministry of Health and Family Welfare (Department of Family Welfare) CH Section

Nirman Bhawan, New Delhi Dated the 26th September, 2002

To

Dr. Tore Godal, Executive Secretary, GAVI, Geneva

Subject:

Submission of Inception Report (First Annual Progress Report)

in respect of Hepatitis B Project supported by GAVI for India.

Sir.

I am directed to enclose herewith the Inception Report (First Annual Progress Report) for October 2001 to September 2002 in respect of Hepatitis B Project supported by GAVI for India. The report has been signed by the Joint Secretary to the Government of India.

The meeting of the Inter-Agency Coordinating Committee (IACC) will be convened soon and the inception report will be placed before them for signature at that time. As soon as the report is signed by the IACC members, a copy again will be sent to you.

With regards,

Yours faithfully,

(Dr. P. Biswal)

Assistant Commissioner(CH)



Annual Progress Report

to the Global Alliance for Vaccines and Immunization (GAVI) and The Vaccine Fund

by the Government of

		ndia
Date of submission	n:	Sept. 2002
Reporting period: 1st Oc	t. 2001	to 30 th Sept. 2002 (previous calendar year)
(Tick only one): Inception report Yes First annual progress report Second annual progress report Third annual progress report Fourth annual progress report Fifth annual progress report		Financial sustainability plan attached

1. Progress	Report
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(Number of children immunized with current and new vaccines is collected from the WHO/UNICEF Joint Reporting Form (JRF))

To be filled in by the country for each type of support received from GAVI/The Vaccine Fund.

1.1. Immunization Services Not Applicable

1.1.1 Receipt of immunization services funding

Date(s) of receipt of funds

Please report on the progress, including any problems that have been encountered with regard to support for immunization strengthening. Please describe the mechanism for management of these funds, including the role of the Inter-Agency Co-ordinating Committee (ICC).

1.1.2 Statement on use of GAVI/The Vaccine Fund immunization services support

In the past year, the following major areas of activities have been funded with the GAVI/The Vaccine Fund contribution.

A was of immunization convious support	Total amount in US \$	I	el	
Area of immunization services support	Total amount in US \$	Central	District	Service delivery
Vaccines				
Injection supplies				
Personnel				
Transportation				
Maintenance and overheads				
Training				
IEC / social mobilization				
Monitoring and surveillance				
Vehicles				
Cold chain equipment				
Other (specify)				

Please indicate the date(s) of the ICC meeting(s) when the allocation of funds was discussed :

1.1.3 Immun	nization Data Quality Audit (DQA) (If it has been implemented in your country)
A plan of action to i	mprove the reporting system based on the recommendations from the DQA, has been prepared
	YES NO NO
The plan of action he	as been discussed and endorsed by the ICC in the meeting of(Date).
1.2 New & Unde	r-used Vaccines
1.2.1 Receipt	t of new and under-used vaccines Date(s) of receipt of vaccines: 7th.Aug.2002.
Please report on the provided by GAVI/I	e progress, including starting date of vaccinations and any problems that have been encountered with regard to vaccines and supplie The Vaccine Fund.
The vaccination	in 15 Project cities under phase 1 of the project is expected to start from last week of Oct.2002.
1.2.2 Major	activities
Please outline what	major activities have been or will be undertaken to prepare for new vaccine introduction.
The major activi	ties already undertaken:

1.Planning & Orientation Workshop:

- An orientation and planning workshop of the city officials from the 15 project cities was organized by Government of India with assistance from PATH, WHO, UNICEF and other GAVI partners on the 10th of May, 2002.
- The cities were informed about the project implementation and their concerns and issues were addressed by GOI and partners. A draft of the Operations Guide prepared in collaboration by all partners, with GOI was circulated for discussion.

2. Operational Guidelines:

- The Operations Guide was finalized after taking in all inputs from City and project officials from the States by Government of India in collaboration with WHO, UNICEF, PATH and other GAVI partners.

 Other publications prepared for the project in collaboration with W.H.O., UNICEF, PATH and other partners includes:
- Frequently Asked Questions & Answers about Hepatitis B disease & vaccination
- "Breaking New Ground" which provides an overview of the UIP and its integration with the new project for Hepatitis B and injection safety.
- A postal cover was developed by GOI for the project.

3. Project Launch:

• The Prime Minister formally launched the GAVI project on June 10th, 2002 at his residence, where a select group of invitees from national and international partners, and other departments of the government were called. The above documents and cover were released by the Prime Minister.

4. Training:

- Sixty Master Trainers (4 from each city) & 150 trainers (10 from each city) from all the 15 project cities have been trained.
- Printing & dispatch of copies of Training Modules in English & Regional Languages for further training of medical officers and vaccinators in the cities has been done.
- The budget required for each city for the training of Medical Officers & Vaccinators has been approved by Govt. of India.
- The vaccine distribution plan from the Central Medical Store Depots of the country for each of the 15 project cities has been developed.

- Study on Assessment of Cold Chain & Vaccine Wastage Rates (on the basis of DPT 3) & how to avoid shortages. Leading Role & Conduct of activity is planned by WHO-SEARO. The Scope of Work for the Study is being reviewed by GOI.
- Study on assessment of Injection Safety: The study has been assigned to India- CLEN, an independent agency. The study's design and implementation is being monitored by Govt. of India & GAVI partners.

 A presentation on Objectives & Methodology of this Study was made by India CLEN on 9th Sept. 2002, which was attended by GAVI Partners from W.H.O.(Consultant on Hepatitis B), PATH, UNICEF, USAID & European Commission. The representatives of India CLEN (Dr. Narendra Arora) agreed to incorporate suggestions of the GAVI partners for further refining the methodology of the study to the extent possible.

1.2.3Statement on use of GAVI/The Vaccine Fund financial support (US\$100,000) for the introduction of the new vaccine

The following major areas of activities have been funded (specify the amount in US\$) with the GAVI/The Vaccine Fund support:

The Secretary Family Welfare of each state involved in implementation of Hepatitis B Project have been requested to provide due attention for proper launching of the program in project cities under their state. They have also been requested to review the preparations for smooth launching of Hepatitis B vaccination with the nodal officer already nominated & briefed for each city & other important stake holders.

The financial assistance of approx. \$14,600 to the project cities is planned to be disbursed in near future for IEC activities & monitoring of arrangements for effective implementation of the project.

To ensure fast transfer of money on insistence of Govt. of India the fund of US \$ 100,000 for introduction of Hepatitis B vaccine in India has been transferred to the account of South East Asia office of W.H.O. so that as & when requested by Govt. of India the same may be released for already budgeted project activities.

Injection safety Not Applicable

1.3.1 Receipt of injection safety support

Please report on the progress, including any problems that have been encountered with regard to the injection safety support.

1.2.2 Progress of transition plan for safe injections and safe management of sharps waste.

Should include objectives, indicators, main achievements, main constraints and targets for next year.

1.3.3 Statement on use of GAVI/The Vaccine Fund injection safety support (if received in the form of a cash contribution)

The following major areas of activities have been funded (specify the amount) with the GAVI/The Vaccine Fund injection safety support in the past year:

2. Financial sustainability

Inception Report: Outline steps towards the development of a financial sustainability plan

First Annual Report : Submit completed financial sustainability plan Subsequent Reports : Summarize progress on financial sustainability

The preparations done so far for introduction of Hepatitis B vaccination in the universal immunization program of the country have helped us to identify the additional inputs needed by us beyond the support from GAVI for successful implementation of the project. The major areas identified for such inputs include printing & distribution of training materials, organizing training programs for Trainers, Medical Officers & vaccinators, provision of AD syringes for vaccination of infants & pregnant women for all the vaccines under Universal Immunization Program, additional financial & technical assistance for strengthening reach & coverage of immunization services, for improving injection safety & proper disposal of AD syringes & also for strengthening the performance monitoring & reporting system related with immunization services.

The process for quantifying the support needed for above activities has been initiated along with exploring the possibilities of funding from IACC members & donors the areas where the resources available with Govt. of India are found lacking.

3. Request for new and under-used vaccines for year 2003-2004. (indicate forthcoming year)

3.1 Up-dated immunization targets

Confirm/update basic data (= surviving infants, DTP3 targets, New vaccination targets) of the multi-year immunization plan approved with country application: revised Table 4 of approved application form and give reasons for any changes.

Table 1: Baseline and annual targets

Number of	Baseline and targets							
Nullibel Of	2000	2001	2002	2003	2004	2005	2006	2007
Births								
Infants' deaths								
Surviving infants								
Infants vaccinated with DTP3 *								
Infants vaccinated with *(use one row for any new vaccine)								
Wastage rate of ** (new vaccine)								

^{*} Indicate actual number of children vaccinated in past years

If the request for supply for the coming years differs from previously approved plan:

Please indicate the reasons for those changes and, where relevant, the related modifications of targets of children to be vaccinated, wastage rate and type of vaccine. Indicate that UNICEF Supply Division has assured the availability of the new quantity of supply according to new changes. Summarise the related modifications of the activities and of the budgets of the work-plan for introduction of new vaccines and indicate the date of the ICC meeting when the changes were endorsed.

As the vaccination by Hepatitis B vaccine is expected to start from last week of Oct. 2002, we may be able to project the requirement for Oct.2003 to Sept. 2004, by the month of Feb.2003. As we implement the Hepatitis B vaccination in next few months, we will have the actual number of children vaccinated & actual wastage rate observed by us for this vaccine.

^{**} Indicate actual wastage rate obtained in past years

3.2 Confirmed/revised request for new vaccine (to be shared with UNICEF Supply Division) for the year (indicate forthcoming year)

Table 2: Estimated number of doses of vaccine (specify for one presentation only): (Please repeat this table for any other vaccine presentation requested from GAVI/The Vaccine Fund

		Formula	For year
A	Number of children to receive new vaccine		
В	Percentage of vaccines requested from The Vaccine Fund	%	
С	Number of doses per child		
D	Number of doses	A x B/100 x C	
Ε	Estimated wastage factor	(see list in table 3)	
F	Number of doses (incl. wastage)	A x C x E x B/100	
G	Vaccines buffer stock	F x 0.25	
Н	Anticipated vaccines in stock at start of year		
I	Total vaccine doses requested	F+G-H	
J	Number of doses per vial		
K	Number of AD syringes (+ 10% wastage)	(D+G-H) x 1.11	
L	Reconstitution syringes (+ 10% wastage)	I/J x 1.11	
M	Total of safety boxes (+ 10% of extra need)	(K+L)/100 x 1.11	

Remarks

- **Phasing:** Please adjust estimates of target number of children to receive new vaccines, if a phased introduction is intended. If targets for hep B3 and Hib3 differ from DTP3, explanation of the difference should be provided
- Wastage of vaccines: The country would aim for a maximum wastage rate of 25% for the first year with a plan to gradually reduce it to 15% by the third year. For vaccine in single or two-dose vials the maximum wastage allowance is 5%. No maximum limits have been set for yellow fever vaccine in multi-dose vials.
- **Buffer stock:** The buffer stock for vaccines and AD syringes is set at 25%. This is added to the first stock of doses required to introduce the vaccination in any given geographic area. Write zero under other years. In case of a phased introduction with the buffer stock spread over several years, the formula should read: [F number of doses (incl. wastage) received in previous year] * 0.25.
- Anticipated vaccines in stock at start of year.....: It is calculated by deducting the buffer stock received in previous years from the current balance of vaccines in stock.
- **AD syringes:** A wastage factor of 1.11 is applied to the total number of vaccine doses requested from the Fund, <u>excluding</u> the wastage of vaccines.
- **Reconstitution syringes:** it applies only for lyophilized vaccines. Write zero for other vaccines.
- <u>Safety boxes:</u> A multiplying factor of 1.11 is applied to safety boxes to cater for areas where one box will be used for less than 100 syringes

Table 3: Wastage rates and factors

Vaccine wastage rate	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%
Equivalent wastage factor	1.05	1.11	1.18	1.25	1.33	1.43	1.54	1.67	1.82	2.00	2.22	2.50

3.3 Confirmed/revised request for injection safety support Not Applicable

(If quantity of current request differs from the GAVI letter of approval, please present the justification for that difference).

Table 4.1: Estimated supplies for safety of vaccination for the next two years with (Use one table for each vaccine BCG, DTP, measles and TT, and number them from 4.1 to 4.4)

		Formula	For year	For year
Α	Target of children for vaccination (for TT : target of pregnant women) ¹	#		
В	Number of doses per child (for TT woman)	#		
С	Number of doses	AxB		
D	AD syringes (+10% wastage)	C x 1.11		
Е	AD syringes buffer stock ²	D x 0.25		
F	Total AD syringes	D+E		
G	Number of doses per vial	#		
Н	Vaccine wastage factor ³	Either 2 or 1.6		
I	Number of reconstitution ⁴ syringes (+10% wastage)	C x H x 1.11/G		
J	Number of safety boxes (+10% of extra need)	(F+I) x 1.11/100		

Table 5: Summary of total supplies for safety of vaccinations with BCG, DTP, TT and measles for the next two years.

ITEM		For the year	For the year	Justification of changes from originally approved supply:
Total AD curingos	for BCG			
Total AD syringes for other vaccines				
Total of reconstitution syri	inges			
Total of safety boxes	, ,			

GAVI will fund the procurement of AD syringes to deliver 2 doses of TT to pregnant women. If the immunization policy of the country includes all Women of Child Bearing Age (WCBA), GAVI/The Vaccine Fund will contribute to a maximum of 2 doses for Pregnant Women (estimated as total births).

The buffer stock for vaccines and AD syringes is set at 25%. This is added to the first stock of doses required to introduce the vaccination in any given geographic area. Write zero for other years.

³ Standard wastage factor will be used for calculation of re-constitution syringes. It will be 2 for BCG, 1.6 for measles and YF.

⁴ Only for lyophilized vaccines. Write zero for other vaccines

Signatures

For the Go	overnment of India	
Signature:	MARIA NINA/Joint Secretary	भोदग दानु/GAUTAM BA. ६ संगुक्त सन्धिग/Joint Secretary
Title: Joint	t Secretary, Ministry of Health & Family Welfare,	Govt of India
	नई विल्ली/New Delhi	MIN OF HEALTH & F.W.
Date:	Sept. 2002	

We, the undersigned members of the Inter-Agency Co-ordinating Committee endorse this report. Signature of endorsement of this document does not imply any financial (or legal) commitment on the part of the partner agency or individual.

Financial accountability forms an integral part of GAVI/The Vaccine Fund monitoring of reporting of country performance. It is based on the regular government audit requirements as detailed in the Banking form. The ICC Members confirm that the funds received have been audited and accounted for according to standard government or partner requirements.

Agency/Organisation	Name/Title	Date	Signature	Agency/Organisation	Name/Title	Date	Signature
W.H.O. India	Dr. T. Walia/ W.H.O. Representative to India	Sept.2002	-	DFID	Dr.Ranjana Kumar	Sept.2002	
Gates Children's Vaccine Program at PATH		Sept.2002		EUROPEAN COMMISSION	Health Advisor H.E. Michel Callouet The Ambassador,	Sept.2002	
	Ms. Maria Calvis/	Sept.2002			European Commission		
UNICEF	Country Representative Dr.GNV Ramana /	Sout 2002					
WORLD BANK	Public Health Specialist	Sept.2002					
USAID	Dr. Victor Barbiero / Director PHN	Sept.2002	**				