RE ED ON

20

GAVI Secrétariat

03/329

Dr. B. Kishore,
Assistant Commissioner (CH)
Room No. 211, D wing
Telefax No. 011-2301-7669
E-Mail-acfp@nb.nic.in

Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi –110 011

D.O.22020/9/2003-CH

Dated: September 30, 2003

Subject: Introduction of Hepatitis B Vaccination in India – Annual Progress Report and Application for Expansion in Additional Districts

Dear Dr. Godal,

We are pleased to enclose the Annual Progress Report for the year 2002-03.

In reference to your letters dated March 3rd & 10, July 24 and September 22, 2003, we have the following response for your information and further necessary action.

We appreciate your offer to extend the deadline for our second application for expansion of Hepatitis B vaccination to additional districts of the country. We would try to send our application latest by October 21, 2003. Failing which, we would request you to ensure that the budget and activities for the first year stated in the multiyear application are considered as per the contingency plan for the year 2004-05, as agreed in your letter.

The vaccine requirement for year 2004 and beneficiaries targeted for year 2004 according to this multiyear plan are stated in the Annual Progress Report (under point 3.1 and 3.2) enclosed with our letter.

This multi year expansion proposal will help us to expand the number of beneficiaries each year from 2004 to cover all the districts (~ 610) in the country by the year 2009. This would be as per the maximum time limit permitted for support by the Vaccine Fund.

The Financial Sustainability Plan would require more time to finalize important initiatives like Immunization Strengthening and RCH II Project expected to be decided by the end of the current year. In collaboration with our in-country Partners, we would work with the representatives of the GAVI Financing Task Force to complete this requirement by the first quarter of 2004.

We would like also to address the issue that you have raised around the coverage of infants in the 15 cities. Our request for an interim expansion to cover all children in the 15 cities, as opposed to restricting it to slum areas is based on the following:

- The minutes of the ICC meeting in December 2002 and April 2003, where the ICC members had agreed to cover all the infants in the selected 15 cities, due to the logistical and practical problems in reaching urban slum children only through a few designated centers. This is in continuation to our response sent by the Assistant Commissioner Child Health, Government of India on June 30th, 2003.

- The infants / families in slums where the Hepatitis B vaccination has begun, often access services from facilities not necessarily in the urban slums, but in whatever urban center is more accessible to them. Therefore, there is a demand from officials in these cities to be allowed to expand supplies of Hepatitis B vaccination to all eligible infants accessing services from all urban health centers / posts.

- This will allow access and increased coverage for all newborn infants in the cities. It should be emphasized that this move will allow greater coverage of newborns in low-income families, since these urban primary health centers in the public sector are accessed largely by low income and resource constrained families, since higher income groups use largely the private sector in the urban areas.

- The revised calculations of expected beneficiary infants is based on population figures of the Census 2001, the latest birth rate and district-wise evaluated immunization coverage as per the Rapid Household Survey conducted under the RCH project of the Government of India.

- As mentioned in the form of anticipated vaccines in stock at the beginning of the year under point 3.2 of the Annual Progress Report enclosed with this letter, we are taking due note and caution to revise the vaccine requirement annually, based on actual consumption reported from the field and the balance stock available.

Thanking you and best regards,

Yours sincerely,

Dr. B. Kishore

Assistant Commissioner Child Health
Department of Family Welfare

Final signed report

GAVI
THE GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION

Partnering with The Vaccine Fund

Annual Progress Report

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

by the Government of

INDIA

Date of submission: 30th September 2000
Reporting period: Oct. 2002 to Sept. 2003.

(Tick only one)

Inception report
First annual progress report : Yes
Second annual progress report
Third annual progress report
Fourth annual progress report
Fifth annual progress report

Financial sustainability plan attached - No

1. Progress Report

(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 for India*

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.

Area of immunization services support	Total amount in US $	Proportion of funds by level		
		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 Immunization Data Quality Audit (DQA) *(If it has been implemented in your country)*

A plan of action to improve the reporting system based on the recommendations from the DQA, has been prepared

YES ☐ NO ☐

The plan of action has been discussed and endorsed by the ICC in the meeting of *(Date).*

1.2 New & Under-used Vaccines

1.2.1 Receipt of new and under-used vaccines: Date(s) of receipt of vaccines: Under the New and Under used Vaccines, India was supported for the Introduction of Hepatitis B Vaccines in 15 Metropolitan cities (in the Slum population) and 32 Districts of the country, for children below one year only, as a pilot project. The project was to be introduced in phases - Phase 1A in cities and Phase1B in districts. The supply of Hepatitis B vaccines (first lot) for 15 project cities was received in September, 2002. The supply of vaccines (first lot) for 33 districts and supply (second lot) of vaccines for 15 Project cities was received in September, 2003.

(Please report on the progress, including starting date of vaccinations and any problems that have been encountered with regard to vaccines and supplies provided by GAVI/The Vaccine Fund).

PROJECT PROGRESS

A. Training in 15 cities:

- Sixty Master Trainers (4 from each city) & 150 trainers (10 from each city) from all the 15 project cities were trained in Training of Trainers organized by PATH-CVP and WHO partners (from June –August2002).
  Master Trainer's (4 for each City). (from June –August 2002)
  Trainers training (10 for each City). (from June –August2002)

- Training Modules in English for further training of medical officers and vaccinators in the cities were developed, printed and distributed to all 15 (Mumbai, Vadodara, Bhopal, Indore, Ahmedabad, Pune, Kanpur, Luckhow, Delhi, Jaipur, Chennai, Hyderabad, Bangalore, Kolkatta and Patna) cities (from May-June-August2002) by partners (PATH-CVP, WHO) in consultation with GOI.
- Translation into local languages completed and training modules in regional languages for vaccinators were issued to cities through UNICEF. (from August-September2002).
- The training of medical officers and vaccinators in 12 cities was completed by implementing States (October 2002- December2002) Government of India released an amount of approx US $ 95833 for the trainings in above cities from its own funds from RCH programme.
- The budget required for launch of Hepatitis B project for all 15 cities was released (September, 2002).
- The vaccine distribution for each of the 15 project cities was released to respective Medical Store Depot's (MSD's) for further release to 15 Cities (October 2002).
- The implementation of the Hepatitis B project began in 12 cities (November 2002- March 2003).
- Kanpur has implemented the Hepatitis B project (September 2003)
- Patna & Lucknow have deferred the Hepatitis-B implementation due to their pre-occupation with Pulse Polio eradication Programme in the Country.

B. Logistics and Vaccines

- The vaccine, AD syringes and safety boxes were received on time.
- There were no major problems encountered with regard to vaccines and supplies provided by GAVI / The Vaccine Fund.

C. Suggestions & Feed back

Four important suggestions were received as a feedback from the Nodal Officers of Project Cities:

a. The needle of AD syringes in future supplies should be of gauge no. 23 or 24 and that their length should not be more than 0.5 inches.
b. Smaller safety boxes with a capacity to hold 50 AD syringes – that is half the size of the present one would be convenient and easier to carry by vaccinators to outreach sessions.
c. Some mechanism to monitor exposure of vaccine to temperatures below the recommended 2 to 8 degree centigrade will be very useful to guard the vaccine against freezing.
d. Some disposable syringes for reconstitution of BCG and measles vaccine must be provided in future for the districts under Hepatitis B project.

1.2.2 Major activities:

(Please outline what major activities have been or will be undertaken to prepare for new vaccine introduction)

The major activities already undertaken:

Phase 1A

In 15 Project Cities since Oct. 2002. Details as stated below:

Details as given above at 1.2.1

- The Hepatitis B vaccination was started in Hyderabad city by Nov. 2002 & in other 11 cities by Feb. 03.
- Out of the remaining 3 cities of Patna, Kanpur and Lucknow, the training of health functionaries was started in 2 cities (Kanpur & Lucknow) in June –July 2003.
- The late start was due to their preoccupation in polio eradication programme in India.
- Kanpur city has started Hepatitis B immunization activities from September 2003.
- In the city of Lucknow, the trainings of health functionaries are likely to be completed within the month of September 2003 and Hepatitis B immunization is expected to start from October 2003.
- In the remaining one city of Patna in the state of Bihar the training of health functionaries has not started yet, due to their preoccupation in polio eradication.

Phase 1B

In 33 Project districts Activities from October 2002:

- Two Master Trainers and two Nodal Program Officers were trained from each of the 33 project districts on time (April –June 2003).
- Printing and despatch of copies of Training Modules in English and Regional Languages for further training of medical officers and vaccinators in each districts was distributed on time (May –August 2003).
- The budget required for each district for the training of Medical Officers and Vaccinators was disbursed to the states for selected districts by Govt. of India on time (June -July 2003).
- An amount of US $ 2,94,963 was released by Government of India from its own budget for training in above stated 33 districts from RCH programme in June 2003.
- In addition to the 32 districts already selected for Hepatitis B project , one more additional district (the Union Territory of Andaman & Nicobar) was added under the project after the consent of ICC (Inter-Agency Co-ordinating Committee), due to their high prévalence rate of Hepatitis B infection.
- The vaccine distribution plan for supply of vaccine from UNICEF to the Central Medical Store Depots (MSDs) of the country & from MSDs for each of the 33 project districts was developed & shared with UNICEF for release of vaccines. Thereafter the first quarter instalment of vaccine supply has been dispatched for the 33 districts.
- Implementation of Hepatitis B vaccination has been initiated in 3 Districts (Chandrapur , Satara and Ratnagiri) of Maharashtra, District Goa from Goa State and Udhampur District of Jammu and Kashmir State.
- UNICEF has committed to supply AD syringes and safety boxes for vaccines other than Hepatitis B for the Project 33 districts and 15 cities for year 2003.

STUDIES AND ASSESSMENT

- Assessment of Cold Chain and Vaccine Wastage Rates (on the basis of DPT 3) was to be conducted by WHO-SEARO, but could not be initiated. The organisation is being requested for completion of study within year 2004.

- The Study on Assessment of Injection Safety is underway. All primary data collection activities have been completed and data is currently under analysis. Preliminary findings of the study are enclosed as Enclosure 1.

1.2.3 Statement 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:

- From the above support of US $100,000, an amount of approx. $ 57583 was utilized for Orientation & Progress Review Workshops of Program Managers & Training of Trainers for 33 selected districts under the Hepatitis B project.
- An amount of approx. $ 16500 is being disbursed starting Sept. 2003 for IEC activities & monitoring of arrangements for effective implementation of the project in 33 districts in 2003-04.
- The remaining amount of approx 25917 US $ out of US $ 100,000 is being released for the strengthening of Hepatitis B cell in child health division of the Department of Family Welfare, Ministry of Health and Family Welfare, Government of India. This includes purchase of computer equipment and hiring of additional support staff.

1. 3 Injection safety: Except for the safety boxes provided under the project as described on page no. 11, the discussion on injection safety is not applicable under this progress report because this has not been incorporated under GAVI's funding. However addressing injection safety has been initiated by the Government for various childhood vaccinations, including with the help of UNICEF during 2000-2003.

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.

1.2.3 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.

.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:

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 Department of Family Welfare is presently in the process of finalising its integrated Reproductive & Child Health programme phase II (RCH II) for the country with the World Bank. This is expected to be completed by December 2003 or early January 2004. Hepatitis B immunization is to be part of the RCH II programme. Efforts are being made to integrate the plan of supporting the Hepatitis B vaccination in cities and districts after its introduction in a phased manner. The Tenth Five Year Plan envisages an amount of about US $ 67 million for support of Hepatitis B immunization in the Country. (Please see Enclosure 5).

Project planning for this integrated project is currently on going and it is expected to be finalized by end-2003 to early 2004. During the remaining period of this year (October-December 2003), the GOI will continue its consultations with its partners in the ICC and the World Bank to finalize both projects. As part of this preparation, it is expected that the Financial Sustainability Plan will be formulated as part of this process, along with the subsequent application to GAVI and the Vaccine Fund.

3. Request for new and under-used vaccines for year 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 (in Millions)

Number of	Baseline and targets							
	2001 Baseline	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
Births	24.75	23.79	24.17	24.55	24.95	25.34	25.05	25.43[1]
Infants' deaths	1.56	1.26	1.28	1.30	1.32	1.34	1.13	1.14[1]
Surviving infants	23.19	22.53	22.89	23.25	23.62	24.00	23.93	24.29
Infants vaccinated with DTP3 *	14.75	15.49	16.26	17.07	17.93	18.82	19.77	20.75[2]
Infants planned to be covered under Hepatitis B Project		0.64	1.63	3.79	6.51	10.18	13.94	18.16
Infants vaccinated with * *Hepatitis B(1st,2nd &3rd dose)*			0.17[3]	2.41	4.35	7.12	10.20	13.86
Wastage rate of ** Hepatitis B in %.. *(new vaccine)*			35	30	25	25	20	20

* Indicate actual number of children vaccinated in past years

** Indicate actual wastage rate obtained in past years

1. The Population of the country, Birth Rate & Infant Mortality Rate projected for year 2002 to 2016 by the office of Registerar General of India have been used (Reference SRS Bulletin Oct. 2002 & Projection tables enclosed as Encl. 2) for calculating no. of births & Infant deaths stated in the above table. For detailed table presenting the projected population also for each year please see enclosure 3.
2. The no. of Infants vaccinated with DPT3 in year 2001 has been derived by multiplying the no. of surviving infants stated in the fourth row from above in column 2 of the above table, with the vaccination coverage data of 63.6% for DPT3. This data has been reported in the National Report 2000-2001, produced by UNICEF & Ministry of Family Welfare, Govt. of India and titled Coverage Evaluation on Routine Immunization (Enclosed as Encl.4). Thereafter as stated on page 19 in the application to GAVI for the first phase of Hepatitis B Project, every year the target of no. of Infant to be vaccinated with DPT3 has been derived by increasing the target by 5% than the previous year.

3. As in the first phase of the project the vaccination was started late by a year the actual performance shown in year 2003 under 4th column in last but 2nd row against the Infants vaccinated with Hepatitis B, may please be compared with the performance expected in year 2002. This is stated under 3rd column in last but 3rd row against the title- Infants planned to be covered under Hepatitis B Project. In year 2004 the target for coverage by Hepatitis B vaccine has been proposed same as for DPT by multiplying the no. of infants planned to be covered under Hepatitis B Project with 63.6% that is the vaccination coverage evaluated by UNICEF for DPT3. Thereafter every year an increase of 5% has been proposed over the coverage data of the previous year as planned in case of DPT also above under point 2.

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.

3.2 Confirmed/revised request for new vaccine *(to be shared with NICEF Supply Division)* for the year 2004 *(indicate forthcoming year,*

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

		Formula	For year 2004 In million
A	Number of children to receive new vaccine		3.79
B	Percentage of vaccines requested from The Vaccine Fund	*100 %*	100%
C	Number of doses per child	3	
D	Number of doses	*A x B/100 x C*	11.37
E	Estimated wastage factor	*(see list in table 3)*	25%
	Number of doses (incl. wastage)	*x C x E x B/100*	14.21
G	Vaccines buffer stock	*F x 0.25*	1.79[A]
H	Anticipated vaccines in stock at start of year ...	*nil*	5.71
I	Total vaccine doses requested	*F + G - H*	10.29
J	Number of doses per vial	*10*	10
K	Number of AD syringes (+ 10% wastage)	*(D + G – H) x 1.11*	8.27
L	Reconstitution syringes (+ 10% wastage)	*I / J x 1.11*	0.00
M	Total of safety boxes (+ 10% of extra need)	*K + L) / 100 x 1.11*	0.18*

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, excluding the wastage of vaccines.

Reconstitution syringes: it applies only for lyophilized vaccines. Write zero for other vaccines.

Safety boxes: 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

Due to smaller no. of beneficiaries turning up at most of the outreach centres & the smaller safety box being easier to carry for vaccinators we would like to get safety boxes with capacity to carry 50 AD syringes & not 100.

A: The Buffer Stock has been derived by reducing 7.04 million doses (including wastage) received in previous year from the 14.21 million doses stated under item F in the above table & by multiplying the product by 0.25 in conformity with the guidelines mentioned under Remarks along side the table stated above.

3.3 Confirmed/revised request for injection safety support

(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 .....
A	Target of children for ..... vaccination (for TT : target of pregnant women)[1]	#		
B	Number of doses per child (for TT woman)	#		
C	Number of ..... doses	A x B		
D	AD syringes (+10% wastage)	C x 1.11		
E	AD syringes buffer stock [2]	D x 0.25		
F	Total AD syringes	D + E		
G	Number of doses per vial	#		
H	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 syringes	for BCG			
	for other vaccines			

[1] 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).

[2] 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

Total of reconstitution syringes			
Total of safety boxes			

4. Signatures

For the Government of .....

Signature: .....

Title: .....डा० शोभन सरकार.....
Dr. SOBHAN SARKAR
उपायुक्त (सं.ऐ.) Dy. Comm ssioner(CH)
स्वास्थ्य एवं परिवार कल्याण मन्त्रालय
Ministry of Health & F.W.
नई दिल्ली/New Delhi.

Date: .....

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
W.H.O.	Dr. Salim Habayeb, WHO representative to India	30/9/03	
DFID	Ms. Ranjana Kumar Senior Health Advisor	30/09/03	R Kumar
EUROPEAN COMMISSION	Mr. J.P. Mishra Programme Advisor	29.09.03.	
Gates Children's Vaccine Programme at PATH	Ms. Madhu Krishna . Program Coordinator	29.09.03	
UNICEF	Country Representative Ms. Maria Calivis	29.09.03	OIC

Agency/Organisation	Name/Title	Date	Signature
USAID	Dr. Robert Clay Director PHN	30.09.03	
WORLD BANK	J.S. Kang for Sr. Public Health Spec	Sep.30,'03	