GAVI Independent Review Committee, Proposal Team Report, 28 May 2004

The proposal review team of the Independent Review Committee (IRC) met in Geneva from the 24th to the 28th of May 2004 to review country proposals requesting GAVI/Vaccine Fund support.

Outcome of the review

A total of 9 requests were submitted by 6 countries. The proposal team's recommendations are summarized in Table 1, and the financial implications are summarized in Table 2. The Board is requested to review these recommendations and provide its recommendation to the Vaccine Fund Executive Committee.

Summary of approvals to date

The financial implications of these recommendations on country proposals are estimated to be US$ 4,887,500, for the years 2004-05 with a five-year financial commitment of US$ 22,516,500. The total 5-year financial commitments from the Vaccine Fund now total US$ 1,082 million (Annex C).

71 of the 75 countries eligible for GAVI/The Vaccine Fund support have applied and 70 have been approved for at least some types of support. Papua New Guinea, Solomon Islands, Nicaragua, Timor Leste have not yet approached GAVI for support.

Table 1: Summary of recommendations by country

Country	Requesting support for	IRC recommendation
Benin	Injection safety	**Approval** (with clarifications) : • To clarify month of introduction in 2005 : transition from HepB to Pentavalent vaccine • To correct Tables 7.1 and 7.2 : calculations to be based on identified first dose coverage targets infants, not on total births
	Hib	**Approval (with clarifications):** • To provide specific annual targets of indicators listed under section VII 1& 2 • To match targets in Table 6 with those in Table 4
Ethiopia	Hepatitis B	**Re-submission**
Guinea Bissau	Injection safety	**Approval** (with clarifications): • To provide a work plan of ICC for the next 12 months which takes into account specific targets, indicators of programme appraisal and resource mobilization.
Mali	Hib	**Re-submission**
Mauritania	Hepatitis B	**Approval**
Mongolia	Injection safety	**Approval**
	Hepatitis B	**Approval**
	Hib	**Approval**[1]

Table 2: Financial implications in 2004-2005 for proposals recommended for approval (in US$)
(underlined figures subject to change pending receipt of clarifications)

Country	New and Under-used Vaccines (estimate)	Injection Safety (estimate)	Other support (one-time vaccine introduction support)
Mauritania	194,000	-	100,000
Mongolia	196,500	47,000	100,000
Benin	*4,071,000*	*136,000*	-
Guinea Bissau	-	*43,000*	-
Subtotal	4,461,500	226,000	200,000
TOTAL			4,887,500

[1] The full IRC report on Mongolia's proposal is attached as Annex B, considering the current uncertainty of Hib disease burden in Asia.

Annex A

Proposal Review – May 2004
IRC Proposal Review Team

Reviewers present:

Dr. Merceline Dahl-Regis
Chief Medical Officer, Ministry of Health, Bahamas

Dr Stanislava Popova-Doytcheva
Scientist, WHO STC
Bulgaria

Dr Grace Murindwa
Principal Health Planner, Ministry of Health, Uganda

Mr Gordon Larsen
Independent Consultant for EPI, UK
(Not participating in decisions on Injection Safety Support for Benin, Guinea Bissau and Mongolia).

Procedure of the review

Each proposal was reviewed by three reviewers. The first reviewer was responsible to take a leading role. The plenary of IRC discussed and made final judgment on recommendations for each component of request. All proposals were decided on a consensus basis, no vote was used.

A strict observation of conflict of interest among members for individual proposal was taken care of. A member was not involved in the discussion of three proposals.

Annex B: IRC detailed report on Mongolia

MONGOLIA

Mongolia applied to GAVI for support for Immunization Services and for New and under-used vaccines (DTP-hepB) in June 2002. With DTP3 coverage >80% the country was not eligible for ISS.

Mongolia was informed that combined vaccines containing the HepB component were not likely to be available until 2004 or 2005 and that in order to receive support from GAVI for NVS the country had to submit an introduction plan for the new vaccine.

Mongolia applied again for DTP-hepB as well as for Injection Safety support in May 2003. As GAVI Board had decided that the IRC would not review new applications for combination vaccines until the requested vaccine would be available within 18 months from the date of the review, Mongolia was advised to either submit a new proposal according to the most recent GAVI guidelines nearer to the date when tetravalent vaccine would be available (keeping contact with UNICEF Supply Division) or apply to GAVI for monovalent HepB vaccine.

Documentation on Injection Safety provided to the IRC did not follow GAVI recommendations and the country was asked to resubmit its application. Mongolia is now applying for introduction of pentavalent vaccine (DTP-HepB+Hib) and Injection Safety support. The ICC has addressed the recommendations made by the WHO EPI Review (2002) and by the IRC.

GENERAL COMMENTS

Mongolia introduced universal infant immunization with recombinant monovalent hepB vaccine in 1991 starting at birth. The high HepB3 coverage achieved (over 90% since 1998 and over 95% since 2000) and improved injection safety (local production of inexpensive and largely available disposable syringes) together with other social and behavioural changes have contributed to reduction in the acute HBV incidence rate. The Multi-year EPI Plan of Action (1999-2004) set an HBsAg prevalence reduction target (<2% in children below 5 years of age).

Introduction of a Hib-containing vaccine has been discussed by the ICC since its establishments in 2001. National experts consider H.influenzae type b an important cause of high acute respiratory infection morbidity (51% of hospital admissions) and accounts for 31% of mortality of children less than 5 years of age (CU5).

Aiming to assess H.influenzae type b burden, Mongolia introduced sentinel surveillance of invasive infections and H.influenzae laboratory diagnosis in the capital city of Ulaanbaatar where 35% of Mongolian children reside. These activities have been guided by WHO, who also funds lab diagnostics. The incidence of culture confirmed Hib meningitis in 2003 was 31/100,000 children <5 years of age. The majority of cases were 5 to 12 months old. Case fatality ratio of Hib meningitis was 21%.

According to the WHO consultant, “this rate should be considered the minimum incidence of Hib meningitis” in Mongolia. “Adjusting for children who died before reaching hospital or who did not have lumbar puncture, the rate of Hib meningitis is likely to be 39/100,000 CU5. Adjusting for probable meningitis cases that did not have an etiological organism isolated, the incidence of Hib

meningitis may be as high as 74/100,000 CU5, a rate comparable to that seen in the United States and some high incidence countries in Africa prior to Hib vaccine introduction.". Using RAT methodology to estimate overall disease burden, the WHO consultant concludes that Hib is likely to cause 500-1000 cases of pneumonia and meningitis and 70-120 childhood death annually in Mongolia. WHO recommends that if resources can be identified, Hib conjugate vaccine should be introduced in Mongolia.

SPECIFIC COMMENTS

1. ICC

Chaired by the Vice Minister of Health, the ICC was involved in preparing the application documentation.

2. New and under-used vaccines

According to the Strategic Plan for the Introduction of DTP-HepB-Hib vaccine into Mongolian EPI Programme, it is to be introduced in a phased manner (over 3 years), initially targeting 5 of the 9 district of Ulaanbaatar and 5 provinces, starting from 3 January 2005. Thus, Mongolia is asking GAVI support for 7 years. As it is seen from the ICC minutes and the Proposal, JICA will continue supplying the birth dose of HepB monovalent vaccine. The Pentavalent vaccine is to be given at the same age as the subsequent 3 doses of DPT/HepB monovalent vaccines (6, 10 and 14 weeks). A transition policy and a change-over plan are to be developed by September 2004 (p.22 of the Proposal).

The Strategic Plan is well structured and addresses all remarks and recommendations of the IRC from the May 2003 review (e.g. reducing vaccine wastage, preventing overstocking, situation resulting from phasing in, etc). The ICC states that the country cold chain can accommodate the new vaccine by changing frequency of deliveries of vaccines to and from the national cold store. The fact that Mongolia did not experience cold chain insufficiency during recent mass measles and diphtheria campaigns further supports the ability of country cold chain to accommodate the pentavalent vaccine.

Quantities of the DTP-HepB+Hib vaccine by years of the GAVI support need to be recalculated. Buffer stock will be received only during the phasing in period (2005-2007) for the initial and then for the added vaccine supplies each year.

3. Injection Safety

A Rapid Assessment of Injection Practices in Mongolia (September 2001) showed that availability of locally-produced inexpensive standard disposable syringes and their universal use for therapeutic and immunization injections and other invasive procedures has significantly diminished the risk of cross infections with blood-borne pathogens among injection recipients. The assessment found that health care workers are at substantial risk of infection due to unsafe practices (recapping needles, emptying safety boxes and counting injection equipment) despite high awareness of HBV and HIV spread through accidental injuries. Safety boxes are inconsistently used and are often regarded as reusable garbage bins. Open burning in drums/stoves seems to be the universal method for destruction of used injection equipment. Safety boxes used for collection of injection equipment during outreach visits are usually dumped in open areas.

Auto-disable syringes (ADs) were used only during a recent measles immunization campaign.

The National Policy on Injection Safety is a satisfactory document. It sets a goal of ensuring usage of ADs for any immunization purposes (fixed, mobile, mass campaign) by the end of 2005. The National Policy addresses safe disposal of used injection equipment. All vaccination centers and mobile teams are to be supplied with safety boxes (SBs) by the end of 2004. Mongolia has produced a pilot series of safety boxes.

National experts believe that Mongolia can meet its needs of ADs, disposable syringes and SBs after the ending of GAVI support. However, national policy on destruction of used injection equipment lacks details. Progressive installation of high temperature incinerators is envisaged from 2005 with two facilities in Ulaanbaatar. The document is also not in full compliance with WHO/UNICEF/UNFPA statement (1999). "Bundling" strategy is to be applied in supplying vaccines for not only mass but routine vaccination too.

The Plan of Action (2004-2008) on Injection Safety is a very good document. Activities of the work-plan have indicators and targets, permitting progress to be measured. Estimates of items to be provided by GAVI need to be corrected as follows. GAVI/VF policy is to provide injection equipment and SBs for the implementation of the WHO standard immunization schedule (children <12 months of age), i.e. one dose of BCG, one dose of HepB monovalent vaccine, three doses of DPT and one dose of measles vaccine. Mongolia is also eligible for 2 doses of DT (instead of TT given to other countries). New and under-used vaccines are supplied in "bundle". Buffer stock of injection equipment for all antigens except DTP-HepB+Hib is valid for the first year of the support only. "Buffer" ADs will be given for three years for the pentavalent vaccine (during "phasing in").

CONCLUSION:
Mongolia has achieved an enormous progress in less than one year time. The MOH, national experts and ICC members are to be congratulated for producing a good quality application.

RECOMMENDATIONS:

Introduction of new and under-used vaccine (DTP-HepB+Hib)-Approval
Injection Safety equipment -Approval

ANNEX C: ESTIMATE OF FIVE-YEAR COMMITMENT IN US$ *(20 June 2004)*

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
1	**Afghanistan**	ISS	7,255,000	7,255,000
		NVS		
		INS	1,619,000	1,619,000
2	**Albania**	ISS		
		NVS	452,000	452,000
		INS	102,000	102,000
3	**Angola**	ISS	6,565,000	6,565,000
		NVS		
		INS	1,525,000	1,525,000
4	**Armenia**	ISS	60,000	60,000
		NVS	437,000	437,000
		INS	54,500	54,500
5	**Azerbaijan**	ISS	487,500	487,500
		NVS	779,500	779,500
		INS	145,000	145,000
6	**Bangladesh**	ISS	26,935,500	26,935,500
		NVS	16,536,500	16,536,500
		INS	8,204,500	8,204,500
7	**Benin**	ISS		
		NVS	2,771,000	20,380,000
		INS		415,000
8	**Bhutan**	ISS		
		NVS	490,000	490,000
		INS	29,000	29,000
9	**Bolivia**	ISS		
		NVS		
		INS	665,000	665,000
10	**Bosnia & Herz**	ISS		
		NVS	359,500	359,500
		INS		
11	**Burkina Faso**	ISS	4,410,500	4,410,500
		NVS		
		INS	834,500	834,500
12	**Burundi**	ISS	2,662,500	2,662,500
		NVS	18,830,000	18,830,000
		INS	428,000	428,000
13	**Cambodia**	ISS	3,012,500	3,012,500
		NVS	6,129,000	6,129,000
		INS	667,500	667,500
14	**Cameroon**	ISS	5,557,000	5,557,000
		NVS	8,483,000	8,483,000
		INS	1,108,500	1,108,500
15	**Central Afr Rep**	ISS	1,837,000	1,837,000
		NVS	730,000	730,000
		INS	156,000	156,000
16	**Chad**	ISS	2,715,000	2,715,000
		NVS	1,251,500	1,251,500
		INS	421,500	421,500
17	**China**	ISS		
		NVS	22,753,500	22,753,500
		INS	15,926,000	15,926,000
18	**Comoros**	ISS	173,500	173,500
		NVS	235,500	235,500
		INS	37,000	37,000
19	**Congo DRC**	ISS	31,298,500	31,298,500
		NVS	11,694,000	11,694,000
		INS	3,238,000	3,238,000
20	**Congo Rep**	ISS	1,534,500	1,534,500
		NVS	896,500	896,500
		INS	266,500	266,500

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
21	**Côte d'Ivoire**	ISS	3,859,500	3,859,500
		NVS	8,057,500	8,057,500
		INS		
22	**Cuba**	ISS		
		NVS		
		INS		
23	**Djibouti**	ISS	271,000	271,000
		NVS		
		INS	32,000	32,000
24	**East Timor**	ISS		
		NVS		
		INS		
25	**Eritrea**	ISS	930,500	930,500
		NVS	2,188,500	2,188,500
		INS	147,000	147,000
26	**Ethiopia**	ISS	19,130,000	19,130,000
		NVS		
		INS	3,091,000	3,091,000
27	**Gambia**	ISS	489,500	489,500
		NVS	3,387,000	3,387,000
		INS	109,000	109,000
28	**Georgia**	ISS	341,000	341,000
		NVS	700,500	700,500
		INS	60,000	60,000
29	**Ghana**	ISS	2,888,000	2,888,000
		NVS	44,121,000	44,121,000
		INS	824,500	824,500
30	**Guinea**	ISS	2,585,500	2,585,500
		NVS	1,112,000	1,112,000
		INS	645,500	645,500
31	**Guinea-Bissau**	ISS	423,000	423,000
		NVS		
		INS		123,500
32	**Guyana**	ISS		
		NVS	1,117,500	1,117,500
		INS		
33	**Haiti**	ISS	2,171,000	2,171,000
		NVS		
		INS	494,000	494,000
34	**Honduras**	ISS		
		NVS		
		INS	471,500	471,500
35	**India*** **	ISS		
		NVS	4,224,000	4,224,000
		INS		
36	**Indonesia**	ISS	16,362,500	16,362,500
		NVS	13,930,500	13,930,500
		INS	9,707,000	9,707,000
37	**Kenya**	ISS	11,113,500	11,113,500
		NVS	64,983,500	64,983,500
		INS	1,220,000	1,220,000
38	**Korea, DPR**	ISS	3,315,500	3,315,500
		NVS	2,565,000	2,565,000
		INS	761,000	761,000
39	**Kyrgyz Rep**	ISS		
		NVS	1,223,500	1,223,500
		INS	178,000	178,000
40	**Lao PDR**	ISS	2,251,500	2,251,500
		NVS	3,494,500	3,494,500
		INS	279,000	279,000

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
41	**Lesotho**	ISS	517,500	517,500
		NVS	482,500	482,500
		INS	110,500	110,500
42	**Liberia**	ISS	2,405,000	2,405,000
		NVS	633,500	633,500
		INS		
43	**Madagascar**	ISS	4,277,500	4,277,500
		NVS	13,801,500	13,801,500
		INS		
44	**Malawi**	ISS		
		NVS	32,586,000	32,586,000
		INS		
45	**Mali**	ISS	4,426,000	4,426,000
		NVS	3,267,500	3,267,500
		INS	780,500	780,500
46	**Mauritania**	ISS	1,062,000	1,062,000
		NVS		925,000
		INS	201,000	201,000
47	**Moldova**	ISS		
		NVS	442,000	442,000
		INS		
48	**Mongolia**	ISS		
		NVS		3,335,000
		INS		109,000
49	**Mozambique**	ISS	3,291,000	3,291,000
		NVS	15,975,500	15,975,500
		INS	986,000	986,000
50	**Myanmar**	ISS	7,902,500	7,902,500
		NVS	15,278,500	15,278,500
		INS	1,343,000	1,343,000
51	**Nepal**	ISS	4,494,000	4,494,000
		NVS	3,751,500	3,751,500
		INS	1,369,500	1,369,500
52	**Nicaragua**	ISS		
		NVS		
		INS		
53	**Niger**	ISS	5,027,000	5,027,000
		NVS		
		INS	1,012,000	1,012,000
54	**Nigeria**	ISS	53,020,000	53,020,000
		NVS	27,829,500	27,829,500
		INS		
55	**Pakistan**	ISS	32,508,000	32,508,000
		NVS	26,300,000	26,300,000
		INS	9,521,500	9,521,500
56	**Papua N G**	ISS		
		NVS		
		INS		
57	**Rwanda**	ISS	3,728,000	3,728,000
		NVS	21,513,000	21,513,000
		INS	406,000	406,000
58	**São Tomé**	ISS	65,500	65,500
		NVS	166,000	166,000
		INS	11,500	11,500
59	**Senegal**	ISS	3,983,500	3,983,500
		NVS	21,438,000	21,438,000
		INS	749,500	749,500
60	**Sierra Leone**	ISS	2,423,500	2,423,500
		NVS	1,474,500	1,474,500
		INS	312,500	312,500

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
61	**Solomon Isl**	ISS		
		NVS		
		INS		
62	**Somalia**	ISS	3,399,500	3,399,500
		NVS		
		INS	349,000	349,000
63	**Sri Lanka**	ISS		
		NVS	2,456,000	2,456,000
		INS	622,500	622,500
64	**Sudan**	ISS	8,968,500	8,968,500
		NVS	4,801,000	4,801,000
		INS	1,828,000	1,828,000
65	**Tajikistan**	ISS	1,510,500	1,510,500
		NVS	959,000	959,000
		INS	255,500	255,500
66	**Tanzania**	ISS	8,665,500	8,665,500
		NVS	30,178,000	30,178,000
		INS	1,510,000	1,510,000
67	**Togo**	ISS	1,945,500	1,945,500
		NVS	1,035,500	1,035,500
		INS	374,500	374,500
68	**Turkmenistan**	ISS		
		NVS	909,000	909,000
		INS	171,000	171,000
69	**Ukraine**	ISS		
		NVS	2,388,000	2,388,000
		INS	747,500	747,500
70	**Uganda**	ISS	11,794,500	11,794,500
		NVS	74,313,000	74,313,000
		INS	1,338,000	1,338,000
71	**Uzbekistan**	ISS		
		NVS	3,718,500	3,718,500
		INS	809,500	809,500
72	**Viet Nam**	ISS		
		NVS	11,650,000	11,650,000
		INS	3,296,500	3,296,500
73	**Yemen**	ISS	4,342,000	4,342,000
		NVS	44,019,500	44,019,500
		INS	1,238,000	1,238,000
74	**Zambia**	ISS	2,959,500	2,959,500
		NVS	33,591,000	33,591,000
		INS	762,500	762,500
75	**Zimbabwe**	ISS	3,220,000	3,220,000
		NVS		
		INS	1,319,000	1,319,000
	TOTAL	ISS	336,572,500	336,572,500
		NVS	638,891,500	660,760,500
		INS	84,872,000	85,519,500
			1,060,336,000	**1,082,852,500**