



**THE GLOBAL ALLIANCE FOR  
VACCINES & IMMUNIZATION**

Partnering with The Vaccine Fund

20 April 2005

## The Government of Bosnia and Herzegovina

Proposal for support submitted to the

Global Alliance for Vaccines and  
Immunization (GAVI)

and The Vaccine Fund

This document is accompanied by an electronic copy on diskette for your convenience. Please  
~~return an electronic copy with the original, signed hard-copy of the document to~~

GAVI Secretariat; c/o UNICEF, Palais des Nations, 1211 Geneva 10, Switzerland.

Enquiries please to: Dr Julian Lob-Levyt, [jloblevyt@unicef.org](mailto:jloblevyt@unicef.org) or representatives of a GAVI  
partner agency. All documents and attachments must be submitted in English or French.

## 1. Executive Summary

Synopsis of the proposal for additional support for injection safety supplies and for the introduction of Hib Vaccine from GAVI and The Vaccine Fund .

Estimation of Hib Disease burden in Bosnia and Herzegovina has been conducted in summer 2004: WHO experts in cooperation with Ministries of Health in both entities, using RAT ("Rapid Assessment Tool for estimating the local burden of Haemophilus influenzae type B disease" found quite high disease burden among 1-5 year old children in FBiH and RS. The same study proved cost effectiveness of Hib vaccination introduction. Hib vaccine was introduced as a pilot in FBiH in a 2002, but the high cost of four doses of Hib vaccine and serious weaknesses in bacterial meningitis surveillance system, were the main obstacles for successful implementation of Hib vaccination. GAVI support for Hib vaccination in the BiH will open a new avenue for further improvement of preventable disease control, reporting and surveillance system and cost effectiveness of the National Immunization Program.

For the first time, this year, country applies for Injection safety Support. In February and March of 2005, in cooperation with WHO experts national Injection safety assessment has been successfully conducted. This is the first injection safety assessment in the country. Additionally National Injection Safety policy and Action Plan are defined. The injection safety assessment analysis indicated weaknesses in injection safety, and gave reliable arguments for opening discussion regarding medical wastage disposal, a problem that has not been resolved for years. Education and training activities which should take place in Injection safety and its implementation will be important an opportunity for improvement of the safety and quality of services within BiH primary health care sector .The same methodology (used in assessment) can be used for regular follow up of injection safety development in coming years.

Figures essential for the calculation of award amounts should be presented here, including:

Population Bosnia and Herzegovina comprises two entities: the Federation of Bosnia and Herzegovina (FBiH) and Republika Srpska (RS) with the population approximately 3.9 million. There is also the independent administrative District of Brčko with the population of 90 thousand not subordinated to either entity. In 2004 there were 34 930 births and 36 542 'surviving' infants, including children born outside the country, the DTP3 coverage was 84% and the short term target for increased coverage is 93% in 2005 increasing to 97% by 2008. The main strategy for increased coverage ultimately to reach 'all' children include comprehensive immunization programme training of health staff at the advent of introduction of new vaccines (Hib) and injection safety procedures – modelled upon experiences gained during the introduction of Hep B vaccine.

The requested number of doses of Hib vaccine in mono-dose presentation is:  
133712 for 2006, 107488 for 2007, 107744 for 2008, 107872 for 2009 and 107936 for 2010

The preparation of this proposal was initiated and followed up at the ICC-meetings in September and November 2004, in conjunction with the development of the FSP submitted in January 2005, and finalized at two recent meetings in 2005

BiH Proposal for support of Injection safety and Hib vaccine introduction

## 2. Signatures of the Government and the Inter-Agency Co-ordinating Committee

The Government of Bosnia and Herzegovina commits itself to developing national immunization services on a sustainable basis in accordance with the multi-year plan submitted with the original proposal in 2002 and as amended by this document. Districts' performance on immunization is reviewed annually through a transparent monitoring system. The Government requests that the Alliance and its partners contribute financial and technical assistance to support immunization of children as outlined in this application.

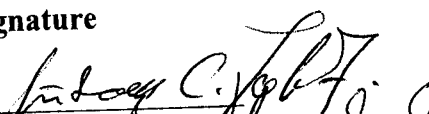

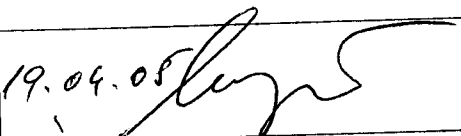
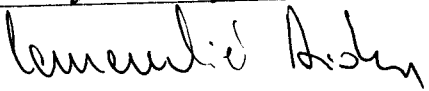

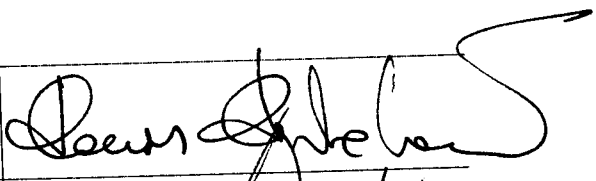

Signature: ..... *S. Hadzihasanovic* ^ .....

Title: ....Minister of Civil Affairs

Date: ..... *21.04.2006* .....

*The GAVI Secretariat is unable to return submitted documents and attachments to individual countries. Unless otherwise specified, documents may be shared with the GAVI partners and collaborators.*

We, the undersigned members of the Inter-Agency Co-ordinating Committee endorse this proposal on the basis of the supporting documentation, which is attached. Signatures for endorsement of this proposal do not imply any financial (or legal) commitment on the part of the partner agency or individual:

Agency/Organisation	Name/Title	Date	Signature
Ministry of Health, RS	Dr.Stevan Jovic	19.04.05	
Ministry of Health, F-BiH	Tomo Lucic/Minister	20.04.05	
Public Health Institute, RS	Director		
	Dr.Mitar Tesanovic/EPI coordinator	19.04.05	
Public Health Institute, F-BiH	Dr.Aida Cemerlic/Deputy Director	19.04.05	
	Prof.Zlatko Puvacic EPI coordinator		
Health, Public Security, and Community Services Brčko District	Head		
	Epidemiologist		
The World Bank BiH office	Representative		
WHO	Haris Hajrulahovic/Liaison Officer		
Unicef	Helena Eversole /Country representative	20.4.05	

In case the GAVI Secretariat have queries on this submission, please contact :

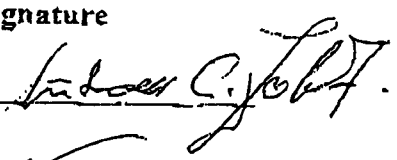
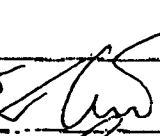
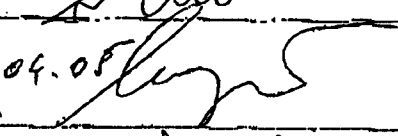
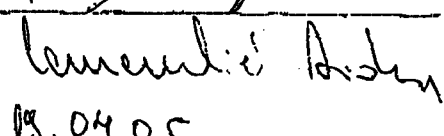
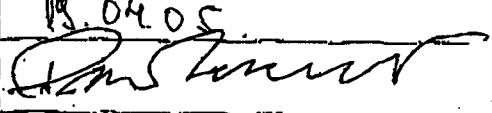
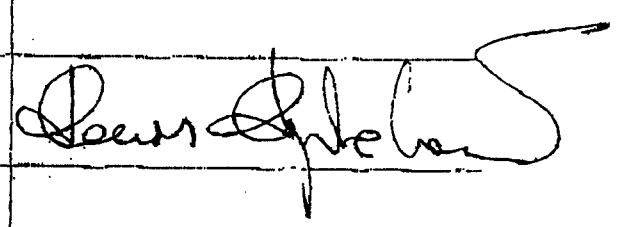
Name:Serifa Godinjak Title/ Dr Address: Ministry of Civil Affairs :Trg BiH, 71 000 Sarajevo

Tel.No +387 33 221 073 ~~check number please~~ Fax No. +387 33 221 074

E-mail: serifa.godinjak@mcp.gov.ba .....

Alternative address:

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	Dr. Mitar Tesanovic/EPI coordinator	19.04.05	
Public Health Institute, F-BiH	Dr. Aida Cemerlic/Deputy Director/Deputy Director	19.04.05	
	Prof. Zlatko Puvacic/EPI coordinator		
Health, Public Security, and Community Services Brčko District	Head		
	Epidemiologist Representative		
The World Bank BiH office			
WHO	Haris Hajrulahovic/Liaison Officer		
Unicef	Helena Eversole/Country representative		

In case the GAVI Secretariat have queries on this submission, please contact :

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E-mail: serifa.godinjak@mcp.gov.ba .....

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 Titova 9, 71000 Sarajevo, Bosnia and Herzegovina  
 Tel.No.: +387 33 220542 Fax No +387 33 664 246  
 E-mail: aida.kapetanovic@fmoh.gov.ba

### 3. Immunization-related fact sheet

See original proposal from 2002

**Table 1: Basic facts** for the year 200... (most recent; specify dates of data provided) See table in original proposal from 2002

Population		GNP per capita	\$US
Surviving Infants*		Infant mortality rate	/ 1000
Percentage of GDP allocated to Health		Percentage of Government expenditure for Health Care	

\* Surviving infants = Infants surviving the first 12 months of life

**Table 2: Trends of immunization coverage and disease burden by 12 months of age** (as per last two annual WHO/UNICEF Joint Reporting Form on Vaccine Preventable Diseases) See table in original proposal from 2002

Trends of immunization coverage (in percentage)							Vaccine preventable disease burden		
Vaccine		Reported		Survey			Disease	Number of reported cases	
		200...	200...	200...	Age group	200...		Age group	200...
BCG							Tuberculosis		
DTP	DTP1						Diphtheria		
	DTP3						Pertussis		
OPV3							Polio		
Measles							Measles		
TT2+ (Pregnant women)							NN Tetanus		
Hib3							Hib		
Yellow Fever							Yellow fever		
HepB3							hepB seroprevalence (if available)		
Vit A supplementation	Mothers (< 6 weeks after delivery)								
	Infants (> 6 months)								

**The best official estimate:** Indicate the best official estimate of coverage among infants as reported in WHO/UNICEF Joint reporting form. Provide explanatory comments on why these are the best estimates: .....

See original proposal from 2002

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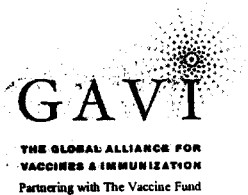
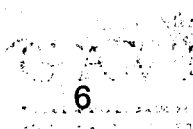
**BiH Proposal for support of Injection safety and Hib vaccine introduction**

- **Summary of health system development status relevant to immunization:  
See original proposal from 2002**

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⇒ Attached are the relevant section(s) of strategies for health system development

Document number.....



#### 4. The Inter Agency Co-ordinating Committee (ICC)

See original proposal from 2002

*Various agencies and partners (including NGOs and Research Institutions) that are supporting immunization services are co-ordinated and organised through an inter-agency co-ordinating mechanism which is referred to in this document as ICC.*

##### 4.1 Profile of the ICC

- Name of the ICC:.....
- Date of constitution of the current ICC:.....
- Organisational structure (e.g., sub-committee, stand-alone):.....
- Frequency of meetings:.....
- Composition: See original proposal from 2002

Function	Title / Organization	Name
Chair		
Secretary		
Members	<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>.....</li> </ul>	



- Major functions and responsibilities of the ICC:  
See original proposal from 2002

Attached is the supporting document:

⇒ Terms of reference of the ICC

Document number.....

- Three major strategies to enhance the ICC's role and functions in the next 12 months:

#### 4.2 Functioning of the ICC

See original proposal from 2002

- Three main indicators (in addition to DTP3 coverage) that are chosen by the ICC to monitor implementation of this proposal :

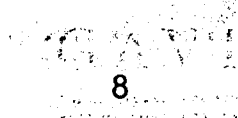
Attached are the supporting documents :

⇒ ICC's workplan for the next 12 months

Document number.....1

⇒ Minutes of the three most recent ICC meetings or of any other meetings in which partners participated that concerned improving and expanding the national immunization program

Document number.....2



## 5. Immunization services assessment(s)

See original proposal from 2002

Reference is made to the most recent assessments of the immunization system that have been completed within the three years prior to the submission of this proposal.

- Assessments, reviews and studies of immunisation services for current reference:

Title of the assessment	Main participating agencies	Dates

- The three major strengths identified in the assessments:

- The three major problems identified in the assessments:

- The three major recommendations in the assessments:

- Attached are complete copies (with an executive summary) of:

⇒ The most recent assessment reports on the status of immunization services

Document number.....

⇒ A list of the recommendations of the assessment reports with remarks on the status of their implementation i.e. included in work-plan, implemented, not implemented, in progress....

Document number.....

- Components or areas of immunization services that are yet to be reviewed (or studied).

Component or area	Month/Year

## 6. Multi-Year Immunization Plan

See original proposal from 2002

Based upon the recommendations of the assessment of immunization services, the Government has developed (or updated) the multi-year immunization plan or adjusted the health sector plan.

⇒ Attached is a complete copy (with an executive summary) of the comprehensive Multi-Year Immunization Plan or of the relevant pages of the health sector plan.

Document number.....

**Technical support required for implementation of the immunization plan (*expert consultants, training curricula, managerial tools...*)**

Type of technical support	Period for the support	Desired from which agency

**Table 3: Schedule of vaccinations with traditional and new vaccines, and with Vit A supplementation**  
See original proposal from 2002

Vaccine <i>(do not use trade name)</i>	Ages of administration <i>(by routine immunization services)</i>	Indicate by an "x" if given in:		Comments
		Entire country	Only part of the country	
Vitamin A				

- Summary of major action points and timeframe for improving immunization coverage:

See Inception Report for 2002 and Annual Progress Report for 2003

**Table 4: Baseline and annual targets**

	Baseline and targets								
	Year of GAVI/VF application	Year 1 of Programme implementation	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8 of Programme implementation
	2002	2003	2004	2005	2006	2007	2008	2009	2010
Births	38861	37180	34 930	34 276	33 948	34 112	34 193	34 234	34 254
thereof births FBIH	24127	23078	22155	21 793	21 899	21 951	21 977	21 990	21 793
Republika Srpska	13754	13204	12676	11 280	11 334	11 361	11 375	11 381	11 280
District Brcko	980	898	862	875	879	881	882	883	875
Infants' deaths	375	322	309	300	302	303	303	303	300
Surviving infants	38486	38065	36542	34755	34923	35007	35048	35069	34755
Infants vaccinated with BCG	35022	34547	33085	33023	33158	33544	33624	33664	33684
BCG coverage*	90%	93%	95%	96%	98%	98%	98%	98%	98%
Infants vaccinated with OPV3	33716		31044	32638	33018	33527	33839	33879	34017
OPV3 coverage**	88%		87%	93%	95%	96%	97%	97%	97%
Infants vaccinated with DTP3***	31005	33186	30188	32638	33018	33527	33839	33879	34017
DTP3 coverage**	81%	87%	84%	93%	95%	96%	97%	97%	97%
Infants vaccinated with DTP1***	33927	35705	33301	33573	33713	34108	34307	34347	34368
Wastage <sup>1</sup> rate in base-year and planned thereafter				25%	25%	25%	25%	25%	25%
Infants vaccinated with 3 <sup>rd</sup> dose of Hep B		10126	12904	33809	33485	33647	33727	33767	33787
Coverage 3 <sup>rd</sup> dose **	0%	79%	81%	96%	96%	96%	96%	96%	96%
Infants vaccinated with 1 <sup>st</sup> dose of Hep B	0	11091	25879	33023	33158	33544	33624	33664	33684
Coverage 1 <sup>st</sup> dose	0%	84%	93%	96%	98%	98%	98%	98%	98%
Estimated Wastage rate of Hep B vaccine, mono-d		5%	5%	5%	5%	5%	5%	5%	5%
Estimated Wastage rate of Hep B vaccine, ten-d			50-60%	25%	25%	25%	25%	25%	25%
Infants vaccinated with 2 <sup>nd</sup> dose of Hib			19095	33809	33485	33647	33727	33767	33787
Coverage			81%	96%	96%	96%	96%	96%	96%
Infants vaccinated with 3 <sup>rd</sup> dose of Hib			11882	34287	33959	34123	34204	34245	34265
Coverage			50%	96%	96%	96%	96%	96%	96%
Estimated Wastage rate of Hib vaccine, mono-d			5%	5%	5%	5%	5%	5%	5%
Infants vaccinated with Measles	36139	20160 <sup>1</sup>	32092	33579	33959	34123	34911	34953	35210
Measles coverage**	89%	81%	88%	94%	96%	96%	98%	98%	99%

\* Number of infants vaccinated out of total births

<sup>1</sup> Data reported only for FBIH

\*\*\* Indicate total number of children vaccinated with either DTP alone or combined

\*\* Number of infants vaccinated out of surviving infants

<sup>1</sup> The formula to calculate a vaccine wastage rate (in percentage):  $[(A - B) / A] \times 100$ . Whereby: A = The number of doses distributed for use according to the supply records with correction for stock balance at the end of the supply period; B = the number of vaccinations with the same vaccine in the same period. For new vaccines check table α after Table 7.1.

**Table 5: Estimate of annual DTP drop out rates** see original proposal from 2002

	Actual rates and targets							
	20...	20...	20...	20...	20...	20...	20...	20...
Drop out rate [(DIP1 - DIP3) / DIP1] x 100								

- Countries requesting YF vaccine have to present the same table for measles vaccine wastage rates.  
NA

- Planning and constraints for the Polio Eradication Initiative:  
see original proposal from 2002

## 7. Injection safety

### 7.1 Summary of the injection safety strategy for immunization (for all proposals):

In BiH up to 600 000 immunization injections are performed each year. There is a need to ensure that the immunization injection services are safe through the correct use of a single sterile needle and syringe for every injection, including proper disposal. In light of this concern, the Ministry of Civil Affairs in collaboration with the Ministry of Health of The Federation of Bosnia-Herzegovina and the Ministry of Health of Republika Srpska, and the administration of District Brčko, have developed a new national policy on injection safety that includes safe disposal. Document 3

This national policy states that 100% of injections given in the public and private sectors for any purpose must be safe.

Briefly, the strategy to improve injection safety for immunization comprises

- A clear definition of a safe injection by aseptic technique, using disposable syringe and needle
- Acceptable equipment for injections
  - Auto-disable<sup>4</sup> syringes to be introduced stepwise to replace the regular disposable syringes
  - Regular disposable syringes are only acceptable for use if taken from sterile packaging immediately prior to injection and safely destroyed after use. Such syringes are still the equipment of choice for therapeutic injections.
- Safe disposal and destruction of used injection equipment by
  - designated safety boxes
  - needles shall not be recapped
  - introduction of an operational system for tracking the distribution, utilization and destruction of injection equipment
  - additional waste from injections shall be disposed of in a different container
  - all used injection equipment will be safely destroyed/removed from harm
    - centralized incineration is the method of choice and requires recollection of safety boxes under specific regulation

<sup>2</sup> The formula to calculate a vaccine wastage rate (in percentage):  $[(A - B) / A] \times 100$ . Whereby: A = The number of doses distributed for use according to the supply records with correction for stock balance at the end of the supply period; B = the number of vaccinations with the same vaccine in the same period. For new vaccines check table  $\alpha$  after Table 7.1.

<sup>3</sup> Formula to calculate DTP vaccine wastage rate (in percentage):  $[(A - B) / A] \times 100$ . Whereby: A = The number of DTP doses distributed for use according to the supply records with correction for stock balance at start and end of the supply period; B = the number of DTP vaccinations.

<sup>4</sup> Auto-disable syringe: Disposable syringe which blocks itself to render it impossible to re-use

- alternatively full safety boxes could be delivered to a specific agency with appropriate means of destruction and/or decontamination of wastes
- for remote health facilities, burial in a specific protected pit is recommended.
- residues from incineration shall be safely buried in a protected pit.
- **Under no circumstances are used syringes or needles, or safety boxes, to be disposed of as regular garbage or randomly dumped**
- Training
  - All health workers will be exposed to the principles of injection safety
    - in-service training of existing health workers
    - Formal training curricula for physicians, pharmacists, nurses and other health workers
- Health staff management and supervision
  - trained and competent people at all levels of the health system are identified and assigned to monitor and manage injection safety issues
- Monitoring of injection practices and AEFI
  - regular monitoring of safe injection practices including sharps safe disposal will be conducted with use of key indicators
- Public awareness
  - Ministries of Health are responsible for providing reliable information on injection safety for medical workers and for the population. A communication strategy with defined priority target groups and communication channels will be developed. Medical workers will inform patients on consequences of unsafe injection.

**7.2 For countries submitting a proposal for Injection Safety Support.** Summarise the most important findings of a recent assessment of Injection Safety and Waste Disposal. The relevant documents are attached.

An injection safety assessment was carried out in Bosnia-Herzegovina in March 2005, in 80 health facilities.

- The three major strengths identified in the assessment:
  1. Disposable syringes were used in all facilities for vaccination and therapeutic injections;
  2. All the injections observed were sterile;
  3. There was no shortage of injection equipment during the last year in 79 (98%) of the 80 health facilities visited.
- The four major problems identified in the assessment:
  1. Two-hand recapping practiced in 23% of the health facilities;
  2. 32% of health facilities reported accidental needle-stick injuries during the last twelve months;
  3. In 61% of the health facilities the syringe and needle were not collected in a safety container immediately after the injection;
  4. In 76% of the health facilities the type of waste disposal for sharps was unsafe.
- The four major recommendations in the assessment:
  1. To introduce Auto-disable syringes stepwise to replace the regular disposable syringes
  2. To ensure a regular and adequate delivery of safety boxes for all immunization injections
  3. To train the health workers on safety procedures, according to the national policy for injection safety and safe disposal
  4. To work and implement a safe health care waste policy

The Plan to achieve Safe Injections (including plans for transition to auto-destruct syringes) and Safe Management of Sharps Waste is attached as Document No. XY.

⇒ Situation Analysis of Injection Safety and Waste Disposal or Report of the most recent Injection Safety and Waste Disposal Assessment	Document number 5
⇒ Update of the implementation status of recommendations from recent injection safety assessment or injection safety components from a broader review.	Document number...
⇒ Policy on Injection Safety and Waste Disposal	Document number 3
⇒ A copy of the Plan to achieve Safe Injections (including plans for transition to auto-destruct syringes) and Safe Management of Sharps Waste	Document number 4

**7.3 Injection safety equipment** (For countries submitting a request for injection safety support). GAVI's support is only for three years of routine immunization.

The following tables calculate the amount of supplies requested for injection safety:

<b>Table 6.1: Estimated supply for safety of vaccination with ...BCG vaccine (1 dose)</b> (Use one table for each vaccine)							
		Formula	2006...	2007...	2008...	2009...	2010...
A	Number of children to be vaccinated <sup>2</sup>	#	33158	33544	33624	33664	33684
B	Percentage of vaccines requested from The Vaccine Fund <sup>3</sup>	%					
C	Number of doses per child	#	1	1	1	1	1
D	Number of doses	$A \times B/100 \times C$	33158	33544	33624	33664	33684
E	Standard vaccine wastage factor <sup>4</sup>	2.0	2	2	2	2	2
F	Number of doses (incl. wastage)	$A \times B/100 \times C \times E$	66315	67089	67249	67329	67369
G	Vaccines buffer stock <sup>5</sup>	$F \times 0.25$	0	0	0	0	0
H	Number of doses per vial	#	20	20	20	20	20
I	Total vaccine doses	$F + G$	66315	67089	67249	67329	67369
J	Number of AD syringes (+ 10% wastage) requested	$(D + G) \times 1.11$	36805	37234	37323	37367	37390
K	Reconstitution syringes (+ 10% wastage) requested <sup>6</sup>	$I/H \times 1.11$	3680	3723	3732	3737	3739
L	Total of safety boxes (+ 10% of extra need) requested	$(J + K) / 100 \times 1.11$	449	455	456	456	457

<sup>2</sup> To insert the number of infants that will complete vaccinations with all scheduled doses of a specific vaccine.  
<sup>3</sup> Estimates of 100% of target number of children is adjusted if a phased-out of GAVI/VF support is intended.  
<sup>4</sup> A standard wastage factor of 2.0 for BCG and of 1.6 for DTP, Measles, TT, and YF vaccines is used for calculation of INS support  
<sup>5</sup> 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 Check. 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.  
<sup>6</sup> It applies only for lyophilized vaccines; write zero for other vaccines.

		Formula	2006...	2007...	2008...	2009...	2010...
A	Number of children to be vaccinated <sup>2</sup>	#	33018	33527	33839	33879	34017
B	Percentage of vaccines requested from The Vaccine Fund <sup>3</sup>	%					
C	Number of doses per child	#	3	3	3	3	3
D	Number of doses	$A \times B / 100 \times C$	99053	100580	101517	101637	102051
E	Standard vaccine wastage factor <sup>4</sup>	<i>Either 2.0 or 1.6</i>	1,6	1,6	1,6	1,6	1,6
F	Number of doses (incl. wastage)	$A \times B / 100 \times C \times E$	158484	160927	162426	162620	163282
G	Vaccines buffer stock <sup>5</sup>	$F \times 0.25$	0	0	0	0	0
H	Number of doses per vial	#	10	10	10	10	10
I	Total vaccine doses	$F + G$	158484	160927	162426	162620	163282
J	Number of AD syringes (+ 10% wastage) requested	$(D + G) \times 1.11$	109948	111643	112683	112817	113277
K	Reconstitution syringes (+ 10% wastage) requested <sup>6</sup>	0	0	0	0	0	0
L	Total of safety boxes (+ 10% of extra need) requested	$(J + K) / 100 \times 1.11$	1220	1239	1251	1252	1257

<sup>2</sup> To insert the number of infants that will complete vaccinations with all scheduled doses of a specific vaccine.  
<sup>3</sup> Estimates of 100% of target number of children is adjusted if a phased-out of GAVI/VF support is intended.  
<sup>4</sup> A standard wastage factor of 2.0 for BCG and of 1.6 for DTP, Measles, TT, and YF vaccines is used for calculation of INS support  
<sup>5</sup> 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.  
<sup>6</sup> It applies only for lyophilized vaccines; write zero for other vaccines.

		Formula	2006...	2007...	2008...	2009...	2010...
A	Number of children to be vaccinated <sup>2</sup>	#	33959	34123	34911	34953	35210
B	Percentage of vaccines requested from The Vaccine Fund <sup>3</sup>	%					
C	Number of doses per child	#	1	1	1	1	1
D	Number of doses	$A \times B / 100 \times C$	33959	34123	34911	34953	35210
E	Standard vaccine wastage factor <sup>4</sup>	<i>Either 2.0 or 1.6</i>	1,6	1,6	1,6	1,6	1,6
F	Number of doses (incl. wastage)	$A \times B / 100 \times C \times E$	54334	54597	55858	55925	56336
G	Vaccines buffer stock <sup>5</sup>	$F \times 0.25$	0	0	0	0	0
H	Number of doses per vial	#	20	20	20	20	20
I	Total vaccine doses	$F + G$	54334	54597	55858	55925	56336
J	Number of AD syringes (+ 10% wastage) requested	$(D + G) \times 1.11$	37694	37877	38752	38798	39083
K	Reconstitution syringes (+ 10% wastage) requested <sup>6</sup>	$I / H \times 1.11$	3016	3030	3100	3104	3127
L	Total of safety boxes (+ 10% of extra need) requested	$(J + K) / 100 \times 1.11$	452	454	465	465	469

Foot notes – see table 6.2



7.4 For countries requesting GAVI/The Vaccine Fund to provide funds in lieu of the supply calculated above. NA

## 8. New and under-used vaccines

- Summary of those aspects of the comprehensive multi-year immunization plan that refer to the introduction of new and under-used vaccines.

•

### **Neonatal Hepatitis B vaccination** (see also original proposal from 2002.)

- Bosnia and Herzegovina's application for the introduction of the HepB vaccine at birth was approved by GAVI in March 2002.
- The entity of Republika Srpska (RS) started with vaccination according to the developed plan in January 2003. After a training seminar in December 2003, District Brcko introduced neonatal HepB vaccination in January 2004.
- The Entity of the Federation of Bosnia and Herzegovina (FbiH) introduced HepB at birth in May 2004. The delay was related to partial disruption of the immunization programme in FbiH precipitated by an extensive media coverage in 2002 questioning the use of donated vaccines, in particular DTP whole-cell vaccine, resistance by paediatricians to the introduction of the HepB vaccine with thiomersal on birth, in parallel with major changes in the programme (pilot introduction of four doses of Hib-vaccine and two booster doses of acellular DTP vaccine (DTPa)). The issues were analysed and resolved after a management review of the immunization programme in the FbiH conducted 2-10 June 2003.
- The MoH in FbiH used the introduction of neonatal Hep B vaccination to strengthen the management of the programme: appointment of an immunization coordinator at the MoH, FbiH, establishing of an Independent Advisory Group on Immunization, improved communication between Federal and Cantonal levels and decentralised training sessions for health personnel regarding Hep B Disease, Hep B Vaccination strategies, Hib vaccination Strategies, injection safety and communication regarding common immunization concerns. The immunization schedule was remodelled and simplified to include three doses of Hep B (one dose of Hib and one dose of DTPa were discontinued).
- Hepatitis B vaccination within 24 hours of birth was rapidly accepted at all maternity wards. Coverage during the 8 first months of the programme in FbiH was 90%, and the coverage of concomitant BCG vaccination rose 2 percentage points to 93%.

### **Vaccination against Hib disease:**

In the original proposal to GAVI in 2002 the MULTI-YEAR STRATEGIC PLAN FOR IMMUNIZATION (2002 – 2006) addressed Hib disease in Objective 11:

“Assessing Hib infection burden and planning for universal childhood immunization” as follows

#### **Feasibility:**

- The MOHs [are] well aware of other countries' findings on H.influenzae type b (Hib) as a major etiological agent of bacterial meningitis and other invasive disorders (epiglottitis, pneumonia, otitis media, osteomyelitis etc.) in infants and young children.
- The MOHs aware of universal or recommended immunization in other countries of the European Region, including neighbour ones with similar to BiH childhood clinical pathology. MOHs willing to introduce universal infant immunization

#### **Challenges:**

- Lack of laboratory diagnosis of H.influenzae
- No data suggesting clinical significance of Hib, needed for the vaccine promotion and its acceptance by the medical community and the general public
- Not affordable for the Government at the present economic situation of BiH

The MoH in the Federation and experts at the Federal Public Health Institute moved swiftly to pilot introduction of Hib vaccination, incorporating Hib vaccine in the vaccination programme Decree for 2003 in FBiH. RS and District Brčko waited for the results of the Hib RAT assessment in July 2004 before taking a decision.

- Assessment of burden of relevant diseases (*if available*) :

Disease	Title of the assessment	Date	Results
Hib	Estimation of Hib Disease Burden in Bosnia and Herzegovina	20-30 July 2004	Disease burden relatively high, introduction of Hib-vaccination may be cost effective and justifiable
			Document 6

**The results from the Hib RAT assessment indicated that Hib-related disease burden in BiH is relatively high, and introduction of Hib vaccine into routine infant immunization may be cost-effective in preventing the morbidity and mortality of severe Hib infection.**

These results were presented and discussed at an International Immunization programme Conference organized by the MoH and PHI of FBiH in Neum, 9-11 September 2004.

There is a clear consensus among national immunization experts and the political leadership (Ministers of Health in the Entities and Cantons) that

- the immunization programme (since long) is considered as a major public health priority, and that
- the introduction of Hib should be endorsed.
- However, the preliminary experiences of Hib vaccination in FBiH (see below) have indicated the vulnerability of the Hib vaccination programme if financial means are not secured and the number of dose per child is not kept at a minimum. Purchasing Hib-vaccine by regular competitive tenders is not considered to be financially sustainable. See the recently prepared Financial Sustainability Plan, Document ZZ
- The Advise from WHO on strengthening of Hib disease laboratory diagnostics should be followed (Document 7). Further technical assistance will be sought to achieve this aim.

The Ministries of Health, together with the immunization partner agencies, in the ICC thus recommend introduction of Hib vaccination if GAVI will support the programme for a period of five years and Unicef procurement will be used thereafter. Else, it will not be feasible to start Hib vaccination in RS, and there is a clear risk that FBiH has to discontinue Hib vaccination.application with special emphasis on other public health priorities, other vaccines under development, financial sustainability, current performance of immunization programme, Hib supply situation, product selection, and operational issues.

- (*For Europe and Asia countries requesting support for Hib Vaccines*). WHO advise on Hib introduction is attached:

⇒ WHO advise on introduction of Hib in this country

Document number...7...

- (*if new or under-used vaccines have been already introduced*)  
Lessons learnt about storage capacity, protection from accidental freezing, staff training, cold chain, logistics, drop out rate, wastage rate etc. as per current experience with new and under-used vaccines:

The pilot introduction of Hib vaccination in the FBiH during 2003 revealed weaknesses in the procurement process and stock management:

For various reasons procurement was done several months before the publication of the decree where four doses of Hib vaccine were included in the vaccination programme.

The manufacturer delivered a Hib vaccine batch with short expiry date (a one year supply had to be used within 2 months after introduction)

Retesting of the batch to permit extension of expiry date was not performed due to the ongoing media debate on other immunization issues.

Difficulties to monitor vaccine stocks in the periphery further hindered redistribution of vaccines between health centres

**Lessons learned:**

Procurement through tendering needs to be planned well in advance in coordination with changes in the immunization programme. Procurement through Unicef may resolve this issue. Potential extension of expiry dates after appropriate testing of vaccine samples from the field should be considered in dialogue between immunization managers, manufacturers and Control Agencies could Stock monitoring and regular feed back is of prime importance if Hib vaccine is introduced in the whole country.

- Summary of the action points that address possible implications for storage capacity, staff training, cold chain, measures to avoid freezing of vaccines, logistics, drop out rate, wastage rate etc... in the Plan for Introduction of New and Under-used Vaccines :

*Actions to be taken*

- Revise immunization programme Decree for 2006 in Republika Srpska to include three doses of mono-valent Hib vaccine at 2, 4 and 12 to 18 months of age
- Complete comprehensive training programs and community mobilization plans
- Preparation, legal and logistic, of procurement of Hib and other vaccines through UNICEF
- Commencement of immunizations using the Hib vaccine from January 2006 in Republika Srpska
- Development of surveillance framework for rapid monitoring of Hib disease prevalence in both entities and District Brčko

*Auxiliary measures*

- Revision, production and parallel introduction of new immunization record forms , as incorporated in the Immunization Programme Decree 2005 for FbiH.
- Development of distribution schedule for AD syringes for all EPI vaccine
- Development of new vaccine replenishment schedule for districts and immunization units
- Development of enhanced supportive supervision procedures

- **First preference:** required number of doses and presentations of requested new and under-used vaccines. (For each one of the requested first preference of new and under-used vaccine, please use provided formulae)

**Table 7.1: Estimated number of doses of Hib vaccine**

	Formula	2006	2007	2008	2009	2010	
A	Number of children to be vaccinated with the first dose <sup>1</sup>	#	33959	34123	34204	34245	34265
B	Percentage of vaccines requested from The Vaccine Fund <sup>2</sup>	%	100	100	100	100	100
C	Number of doses per child	#	3	3	3	3	3
D	Number of doses	$A \times B / 100 \times C$	101876	102369	102613	102735	102796
E	Estimated vaccine wastage factor	see list in table $\alpha$	1.05	1.05	1.05	1.05	1.05
F	Number of doses (incl. wastage)	$D \times E$	106970	107488	107744	107872	107936
G	Vaccines buffer stock <sup>3</sup>	$F (-F \text{ of previous year}) \times 0.25$	26742	0	0	0	0
H	Number of doses per vial	#	1	1	1	1	1
I	Total vaccine doses requested	$F + G$	133712	107488	107744	107872	107936
J	Number of AD syringes (+ 10% wastage)	$(D + G) \times 1.11$	142767	113630	113901	114036	114104
K	Reconstitution syringes (+ 10% wastage) <sup>4</sup>	$I / H \times 1.11$	148421	119311	119596	119738	119809
L	Total of safety boxes (+ 10% of extra need)	$(J + K) / 100 \times 1.11$	3232	2586	2592	2595	2596

- **Table  $\alpha$  : Wastage rates and factors** Countries are expected to plan for a maximum of 50% wastage rate for a lyophilized vaccine in 10 or 20-dose vial, 25% for a liquid vaccine in a10 or 20-dose vial, 10% for any vaccine (either liquid or lyophilized) in 1 or 2-dose vial, and to reduce it in the following years.

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

- Summary of major action points and timeframe for reduction of vaccine wastage. If maximum allowance of wastage rates cannot be achieved immediately, the proposal has to provide a rationale for a higher rate:

NA

- **Second preference:** Required number of doses and presentations of requested new and under-used vaccines, if first preference is not available. (Please use provided formulae as per table 7.1)

For programmatic reasons, introduction of Hib combination vaccines is not considered feasible during the next 5-year period. The vaccination schedule with neonatal Hep B and a minimal number of Hib doses would require different presentations of DTP for dose 1 and 2, and dose 3, respectively.

<sup>8</sup> 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

<sup>9</sup> 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.

<sup>10</sup> 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.

<sup>11</sup> A wastage factor of 1.11 is applied to the total number of vaccine doses requested from the Fund, excluding the wastage of vaccines.

<sup>12</sup> It applies only for lyophilized vaccines. Write zero for other vaccines.

⇒ Attached is the plan of action for introduction of vaccinations with new or under-used vaccines, *specifically Hib* Document number8

## 9. Financial analysis and planning

Assured long term financing is crucial for maintaining program improvements and sustaining the introduction of new vaccines. Meeting the financial requirements of improved and expanded immunization programs has proven to be the biggest challenge that countries and their partners face. The financial analysis of the estimated cost of immunization (including the introduction of a new vaccine) is summarised in three major areas for the next years (see the document attached hereby):

1. Rigorous analyses of the current and projected future costs for the program for the next years;
2. Projected financing from all sources for the same time period;
3. Description of the highest priority actions that the government/ will take to fill any resource gaps.

- For countries that have already completed a Financial Sustainability Plan (FSP):

⇒ The attached document is an update of the program costs, financing projections and the plan of action for addressing the financial gap *(if already contained within the national, comprehensive multi-year plan, indicate pages)* Document number NA...

BiH submitted the FSP on 31 January 2005 and the Government would appreciate comments on this plan before the plan is revised and updated regarding projected future costs, financing and priority actions

- For countries that have not completed a FSP:

⇒ The attached document summarises the results of most recent efforts to conduct the needed financial analyses and prepare a FSP. *(if already contained within the national, comprehensive multi-year plan, indicate pages)* Document number.....

Please follow the latest version of the financial analysis tool which is available @ [http://www.who.int/immunization\\_financing/tools/annexes/en/](http://www.who.int/immunization_financing/tools/annexes/en/)

## 10. Summary of requests to GAVI and the Vaccine Fund

With reference to all points presented above, the Government of Bosnia and Herzegovina,

considering that its DTP3 coverage for 20 was 84% corresponding to 30188 number of children receiving 3 doses of DTP, requests the Alliance and its partners to contribute financial and technical assistance required to increase immunization of children.

Specifically, the Government hereby applies for the following types of support from GAVI and the Vaccine Fund. *(Circle "YES" or "NO" according to the requests submitted with this proposal):*

- |  |                |               |
|--|----------------|---------------|
| • <i>Support for Immunization Services</i>       | <del>YES</del> | NO            |
| • <i>Support for New and Under-used vaccines</i> | YES            | <del>NO</del> |
| • <i>Support for Injection Safety</i>            | YES            | <del>NO</del> |

### 10.1 SUPPORT FOR IMMUNIZATION SERVICES

GAVI and the Vaccine Fund are requested to fund the strategies for strengthening immunization services in year 20...according to the number of additional children (as compared to the baseline) that are targeted to be immunized with DTP3 as presented in table 4, namely ..... (number of children). Funds will also be requested for following years as estimated in table 4.

- The Government takes full responsibility to manage the in-country transfer of funds.  
(In case an alternative mechanism is necessary please describe it and the reasons for it:)
- Operational mechanism that is followed for safeguarding transparency, standards of accounting, long-term sustainability and empowerment of the government in using the funds:
- Countries requesting immunization services support should submit the "Banking Details" form (Annex 2) with their proposal.

### 10.2 SUPPORT FOR NEW AND UNDER-USED VACCINES

GAVI and the Vaccine Fund are requested to fund the introduction of New and Under-used Vaccines by providing the following vaccines: (fill in only what is being requested from the Vaccine Fund in line with tables 7.1...)

**Table 8: New and under-used vaccines requested from GAVI and the Vaccine Fund** (fill in the annual amount of row "I" of table 7.1. Specify one additional row for each presentation of any vaccine as per tables 7.2, 7.3, ...)

Vaccine presentation	Number of doses per vial	Starting month and year	Number of doses requested for first calendar year	Number of doses requested for second calendar year *
Hib	1	Jan 2006	133712	107488

- Vaccines will also be requested for following years as described in tables 7.1: 2006, 2007, 2008, 2009, 2010;
- Vaccines will be procured (tick only one) :

By UNICEF  Yes

By GOVERNMENT

- (If vaccines are proposed to be procured by the Government) Process and procedures of the National Regulatory Authority to control the purchase and delivery of vaccines into the country, including weaknesses, constraints and planned measures to improve the control system:
- (In case you are approved, you will be entitled to receive a lump-sum of US\$ 100,000 to facilitate the introduction of new vaccines) Please submit the attached "Banking Form" (Annex 2) with the proposal, in case you have not yet already done so for other types of support from GAVI/The Vaccine Fund..

Not applicable for a second new vaccine

### 10.3 SUPPORT FOR INJECTION SAFETY

GAVI and the Vaccine Fund are requested to support the injection safety plan by providing:

(Tick one choice only):  **Yes The amount of supplies listed in table 9**

**The equivalent amount of funds**

**Table 9: Summary of total supplies for safety of vaccinations with BCG, DTP, and MEASLES, requested from GAVI and the Vaccine Fund for three years (fill in the total sums of rows "J, K and L" of tables 6.1, 6.2, and 6.3.).**

	ITEM		2006	2007	2008	2009
J	Total AD syringes	for BCG	36805	37234	37323	37367
		for other vaccines	75388	75753	77503	77595
K	Total of reconstitution syringes		6031	6060	6200	6208
L	Total of safety boxes		1353	1363	1385	1386

- *(In case you request funds equivalent to the above supplies at the prices obtained by UNICEF) Please submit the attached "Banking Form"(Annex 2) with the proposal, in case you have not yet already done so for other types of support from GAVI/The Vaccine Fund.*

**11. Additional comments and recommendations from the ICC**

See Pending ICC minutes from the meeting 19 April 2005

## Index of documents attached

Section of proposal	Document Subject	Document number
3	A copy of the relevant section(s) of strategies for health system development	NA
4	a) The terms of reference of the ICC	NA
	b) The ICC's workplan for the next 12 months	1
	c) The minutes of the three most recent ICC meetings or any meetings concerning the introduction of new or under-used vaccines or safety of injections	2
5	a) Most recent, national assessment report(s) on the status of immunization services	.....
	b) Summary of the recommendations of the assessment report(s) with remarks on the status of implementation of each recommendation.	.....
6	A complete copy ( <i>with executive summary</i> ) of the comprehensive Multi-Year Immunization Plan or of the relevant pages of the health sector plan	.....
7	a) The Situation Analysis of Injection Safety and Waste Disposal or Report of the most recent Injection Safety and Waste Disposal Assessment	5
	b) An update of the implementation status of recommendations from recent injection safety assessment or injection safety components from a broader review.	.....
	c) The Policy on Injection Safety and Waste Disposal or a Draft Policy awaiting endorsement	3
	d) The plan to achieve Safe Injections ( <i>including plans for transition to auto-destruct syringes</i> ) and Safe Management of Sharps Waste or relevant pages of the health plan.	4
8	a) WHO's advise on introduction of Hib in this country ( <i>for European and Asian countries</i> )	7
	b) Plan of Action for the introduction of new or under-used vaccines into immunization services ( <i>if already contained within the national, multi-year plan, please indicate page and paragraphs</i> )	8
	c) <i>Hib Disease Burden assessment RAT</i>	6
9	Updated Financial Sustainability Plan (or a summary of the relevant financial analysis for preparation of the FSP)	...NA



Not applicable for this proposal

GLOBAL ALLIANCE FOR  
VACCINES AND IMMUNIZATION

Banking Form



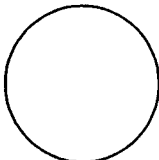
*In accordance with the decision on financial support made by the Global Alliance for Vaccines and Immunization and the Vaccine Fund dated....., the Government of....., hereby requests that a payment be made, via electronic bank transfer, as detailed below:*

<b>Name of Institution:</b> <i>(Account Holder)</i>	.....
<b>Address:</b>	.....
<b>City – Country:</b>	.....
<b>Telephone No.:</b>	<b>Fax No.:</b>
<b>Amount in USD:</b>	<b>Currency of the bank account:</b>
<b>For credit to:</b> <i>Bank account's title</i>	.....
<b>Bank account No.:</b>	.....
<b>At:</b> <i>Bank's name</i>	.....

Is the bank account exclusively to be used by this programme? YES ( ) NO ( )

By whom is the account audited? .....

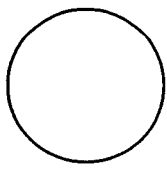
Signature of Government's authorizing official:

<b>Name:</b> .....	<b>Seal:</b> 
<b>Title:</b> .....	
<b>Signature:</b> .....	
<b>Date:</b> .....	



FINANCIAL INSTITUTION	CORRESPONDENT BANK <i>(In the United States)</i>
Bank Name: .....	
Branch Name: .....	
Address: .....	
City – Country: .....	
Swift code: .....	
Sort code: .....	
ABA No.: .....	
Telephone No.: .....	
Fax No.: .....	

I certify that the account No. .... is held by  
*(Institution name)* .....at this banking institution.

<p><b>The account is to be signed jointly by at least ..... (number of signatories) of the following authorized signatories:</b></p> <p>1 Name: .....</p> <p style="padding-left: 20px;">Title: .....</p> <hr/> <p>2 Name: .....</p> <p style="padding-left: 20px;">Title: .....</p> <hr/> <p>3 Name: .....</p> <p style="padding-left: 20px;">Title: .....</p> <hr/> <p>4 Name: .....</p> <p style="padding-left: 20px;">Title: .....</p>	<p><b>Name of bank's authorizing official:</b></p> <p>.....</p> <p><b>Signature:</b> .....</p> <p><b>Date:</b> .....</p> <p><b>Seal:</b></p> <div style="text-align: center; margin-top: 20px;">  </div>
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*(To be completed by UNICEF representative on letter-headed paper)*

**TO: GAVI – Secretariat  
Att. Dr Tore Godal  
Executive Secretary  
C/o UNICEF  
Palais des Nations  
CH 1211 Geneva 10  
Switzerland**

***On the ..... I received the original of the BANKING DETAILS form,  
which is attached.***

***I certify that the form does bear the signatures of the following officials:***

	Name	Title
Government's authorizing official	.....	.....
Bank's authorizing official	.....	.....

**Signature of UNICEF Representative:**

**Name**

.....

**Signature**

.....

**Date**

.....