



Report to the GAVI Alliance Board

7-8 July 2011

Subject:	India: Request for extension of deadline for pentavalent vaccine support
Report of:	Mercy Ahun, Managing Director Programme Delivery
Authored by:	Ranjana Kumar, Senior Specialist Programme Delivery
Agenda item:	06
Category:	For Decision
Strategic goal:	SG 1 – Underused and new vaccines

Section A: Overview

1. Purpose of the report

- 1.1. To seek Board consideration of India's request for an extension to the deadline to submit scaling up plans for the introduction of pentavalent vaccine from 30 June 2011 until 31 December 2011.

2. Recommendations

- 2.1. The Secretariat recommends that the GAVI Alliance Board approve the following resolution:

"The GAVI Alliance Board:

Noted the request by the Government of India to extend the period as set by the Executive Committee to submit a satisfactory plan to introduce DTP-HepB-Hib in additional states (the "Introduction Plan") from 30 June 2011 until 31 December 2011; and

Decided to extend the deadline for the Government of India to submit the Introduction Plan to a date to be agreed by the PPC-appointed Task Team on Large Countries (India and Nigeria), enabling the Task Team to take the Introduction Plan into account in its recommendations to the Board at its next meeting in November 2011. The remaining US\$ 118,500,000 of the NVS programme budget as endorsed by the Executive Committee will be rescinded if the Introduction Plan is not submitted by the agreed date and in any event no later than the November Board meeting."

3. Executive summary

- 3.1. The Executive Committee (EC) approved India's revised plans for introduction of DTP-HepB-Hib pentavalent vaccine in two states in November 2010 with a commitment of US\$ 46,500,000 for the period 2010-2014. This budget was within the overall original endorsement of US\$165,000,000 for introduction of pentavalent vaccine in India, approved by the EC in July 2009. In November 2010, the EC also decided that the remaining US\$ 118,500,000 programme budget and programme liability would be rescinded on or around 30 June 2011 should the Government of India not submit a satisfactory plan to introduce DTP-HepB-Hib in additional states prior to that date.
- 3.2. The Programme and Policy Committee (PPC)-appointed Task Team on Large Countries (India and Nigeria) has begun consultation with the Government of India and other stakeholders on how GAVI can best support immunisation in India. Partly as the result of this process India requested an extension of the above deadline by six months (see Annex A).
- 3.3. It is recommended that the Board approve an extension to the deadline for the Government of India, whereby the Government should submit its Introduction Plan at a date to be agreed by the Task Team, enabling the Task Team to take the Introduction Plan into account in its recommendations to the Board at its next meeting in November 2011. The Task Team has reported positive signs of India's engagement on immunisation including on the introduction of pentavalent vaccine. India has the largest birth cohort and the highest number of unimmunised children in the world, and it is not clear what the impact would be of ceasing the current engagement with India and requesting it to reapply for the pentavalent vaccine. There is a risk that India would not re-apply, or that it would delay re-applying.

4. Context

- 4.1. Previous experience on GAVI support to India has been mixed. GAVI support for injection safety and Hepatitis B monovalent vaccine was positive and has catalysed the adoption of a national policy and nationwide scale up of both the commodities. However, while injection safety was scaled up within 2 years, there were implementation challenges, and scale up plans for Hep B mono took over 8 years. India now procures the vaccine locally with its own resources at less than 30% of the current UNICEF weighted average price for HepB mono.
- 4.2. A brief chronology of India's proposal for the introduction of pentavalent vaccine is as follows:
 - July 2009 – The Executive Committee approved India's application for the introduction of pentavalent for 2010-2011 in 10 States for US\$ 165,000,000;

- June 2010 – The Board delegated the authority to the Secretariat to partially rescind a financial commitment of up to US\$ 165,000,000 in the absence of a satisfactory plan to introduce pentavalent in five states or begin implementation by 1 December 2010;
 - November 2010 – The EC approved India's revised two state proposals for US\$ 46,500,000 and indicated that the remaining balance of the original proposal of US\$ 118,500,000 would be rescinded should India not provide a scale up plan for additional states by 30 June 2011.
 - 13 June 2011 – India requested an extension of the EC deadline for the scale up plan for the introduction of pentavalent vaccine in additional states.
- 4.3. Currently the Task Team on Large Countries is working with India to explore options for strategic support. A report will be presented at the November Board meeting. The policy objectives of the Task Team are:
- (a) To understand country priorities for immunisation that could be advanced through provision of catalytic GAVI support;
 - (b) To understand how GAVI support can contribute to country goals of effective, safe and equitable access to immunization and strong systems in the most impactful manner; and
 - (c) To evaluate the pros and cons of various policy options and how support would be implemented.
- 4.4. If GAVI agrees to a six-month extension a perception may arise that GAVI was not serious about its earlier requests that India move swiftly to introduce pentavalent vaccine or the funds would be re-allocated.
- 4.5. However, India has the largest birth cohort and the highest number of unimmunised children in the world, representing 45% of the global burden, and therefore continued engagement with India is important to GAVI's mission. Early indications from the Task Team are that the national government is actively discussing pentavalent vaccine expansion issues with states and that some states have responded positively. It appears as though the dialogue has shifted in a positive direction. A GAVI decision to reallocate funding of the Indian pentavalent proposal at this stage may negatively affect the recent engagement and positive signs.
- 4.6. Rejecting India's request for an extension would mean that it would need to submit a new proposal for the introduction of pentavalent vaccine in a future round. This would limit the ability of the Task Team to optimise the opportunity of the rapid introduction of pentavalent vaccine beyond the two states in India currently introducing pentavalent vaccine. Extending the deadline for the expansion plan for pentavalent introduction in India will enable the Task Team to take into account any developments in this area in its report to the PPC in September and the Board at its meeting in November.

- 4.7. Several members of the Task Team, including those representing UNICEF and WHO, have indicated their strong support for an extension.
- 4.8. In light of the above, it is recommended that the Board approve an extension to the deadline for the Government of India, whereby the Government should submit its Introduction Plan for pentavalent vaccine at a date to be agreed by the Task Team, enabling the Task Team to take the Introduction Plan into account in its recommendations to the Board at its next meeting in November 2011. This timing will allow a reasonable period for the Government of India to build on progress made.

5. Next steps

- 5.1. The Secretariat will inform the Government of India of the Board's decision and make any necessary adjustments to GAVI programme financing estimates.

6. Conclusions

- 6.1. On balance, the Secretariat considers an extension of the deadline for India to submit a satisfactory plan on the introduction of pentavalent vaccine in additional states should be approved, as described in the recommendation. India will introduce pentavalent vaccine in Tamil Nadu and Kerala by September 2011 and there are indications that progress is being made on the plan for the introduction in additional states. If no plan is submitted in time, the remaining balance of US\$ 118,500,000 will be reallocated.

Section B: Implications

7. Impact on the Business Plan / Budget / Programme Financing

- 7.1. Helps to achieve SG1 targets.

8. Risk implications and mitigations

- 8.1. Agreeing to the India extension request may give the impression that GAVI is prepared to consider further delays.

9. Legal or governance implications

- 9.1. Not applicable.

10. Consultation

- 10.1. The PPC Task Team on Large Countries (India and Nigeria) was consulted on this issue.

11. Gender issues

- 11.1. A recent global study on gender and immunisation reported that although there were no significant sex discrepancies across India in terms of access to vaccines between boys and girls, some of the reports reviewed within the study did show gender inequality and discrimination against girls with regards to vaccination in some states of India. In addition, the study identified gender-related barriers to immunisation services on a local or regional basis.
- 11.2. Since the start of the implementation of the GAVI Gender Policy, the guidelines for new and underused vaccines have been modified with respect to gender issues. India initially submitted its proposal for pentavalent vaccine in accordance with the guidelines and forms for the application round approved in July 2009. In the latest guidelines (for the June 2011 round), countries are requested to provide further information, including a situation analysis of immunisation programmes including social and gender-related barriers to health. On the latest proposal forms, countries are specifically asked about whether sex-disaggregated data is collected and about whether gender aspects relating to introduction of a new vaccine have been addressed in the introduction plan. Granting an extension to India means that unlike other countries applying to roll-out vaccines in the same time period, India would not be required to make available this data on gender. This will be highlighted to the Task Team on Large Countries for its continued discussions with the Government of India.

12. Implications for the Secretariat

- 12.1. If the Board approves an extension for India to submit its introduction plan for pentavalent vaccine, the Secretariat must remain closely engaged with the Government of India on this issue.

ANNEX A: India extension request



Anuradha Gupta, IAS
Joint Secretary
Telefax : 23062157
E-mail : anuradha-gupta@hotmail.com



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110108
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110108

D.O. No. T-22011/1/2011-Imm
Dated : 13th June, 2011

Dear *Ms. Evans,*

This has reference to your letter dated 26th April, 2011 (bearing reference No. GAVI/11/119/rk/sc) addressed to Hon'ble Union Health Minister, Government of India confirming GAVI Executive Committee (EC) endorsement on India's request for introduction of pentavalent vaccine in Tamil Nadu and Kerala and offer for further expansion to some more States.

Matter regarding expansion of Pentavalent Vaccine to more States is under consideration. The process will take some more time.

I shall be grateful, if GAVI Alliance could consider extending the time limit for submitting a proposal by another six months.

With regards,

Yours sincerely,



(Anuradha Gupta)

Ms. Helen Evans
Interim Chief Executive Officer
GAVI Alliance Secretariat
2, Chemin des Mines
1202 Geneva
Switzerland