

FOR DECISION

The Executive Committee approved India for DTP-HepB-Hib pentavalent vaccine in July 2009 with an overall commitment for US\$ 165 million through 2011. Until recently the Indian Government has indicated that it is reconsidering plans to introduce pentavalent vaccine; GAVI indicated to the Government that we would seek the views of the Board at its June meeting as to whether the \$165 million should be reallocated. The latest communication from the Government proposes that the vaccine should be introduced in late 2010 in five states instead of the original ten.

The Board is asked to decide from among the following options:

- Option 1: Reallocate \$165 million to other countries, and invite India to resubmit a new proposal when ready
- Option 2: Agree to the proposal to fund introduction in a limited number of states. This would entail asking India for a new plan which includes costing in the five states. The balance would be reallocated to other countries
- Option 3: Leave the India programme as it stands

GAVI support to India

India has the largest population and disease burden of any GAVI-eligible country. GAVI has made a significant commitment to India with mixed results. Our support for injection safety has catalysed the adoption of a national policy enabling India to sustain the use of safe injection practices entirely with its own resources. The introduction of Hepatitis B on the other hand has been slow.

In November 2007, the Board approved a new financial ceiling of US\$ 350 million until 2011 which subsumed all the previous approvals.¹ India applied for DTP-HepB-Hib pentavalent vaccine, and the Executive Committee approved \$165 million in July 2009.² As India had yet to receive cabinet approval to roll out pentavalent vaccine, UNICEF Supply Division was advised not to ship the vaccines until GAVI received a formal communication from India indicating internal approval.

Summary of communications between GAVI and the Indian Government on the proposed introduction of pentavalent vaccine

- In December 2009, the Government alerted GAVI that the introduction of penta was likely to be delayed because of a Public Interest Litigation (PIL), filed in the Delhi High Court against the introduction of new vaccines citing the lack of disease burden as one of the key factors.
- In February 2010, India wrote to GAVI stating, '*several procedural issues and approvals are involved before introduction of pentavalent vaccine as part of the routine immunisation programme. It will take us 4 months to finalise the matter*'.³

¹ Section 17 of the 28-29 November 2007 Board Minutes

² Section 2 of the 30 July 2009 Executive Committee Minutes

³ Letter received by Executive Office on 12 February 2010

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- In March 2010, the CEO wrote to the Government that, in the context of the Board's decision in Hanoi to review the October 2009 IRC recommendations, *'GAVI is currently facing a funding challenge, and is working hard to secure more funding, and we are required to report to the Board on delays in using any committed funds of significant value. GAVI's allocation of \$165 million to India for pentavalent vaccines is one of the largest single commitments to any country. Should India be unable to approve the introduction of the vaccine by June we will need to seek our Board's advice as to whether the funds should be reallocated.'*⁴
- India responded in May 2010 requesting assured commitment of GAVI funds until end July, stating that, *'the matter of introduction of pentavalent vaccine has become sub-judice now and the court hearing is slated for 28 July 2010. This is also being reviewed by a Core Committee under the chairmanship of Secretary Department of Biotechnology (DBT) and their recommendations are awaited'*.⁵
- Following the Core Committee's recommendations, India informed GAVI on 8 June that, *'we are taking steps for introduction of Pentavalent vaccine soon in five states which will account for an estimated 2.97 million children being covered. Thereafter, the Pentavalent vaccine will be rolled out to other States. We expect to complete the process of obtaining requisite approval of accepting GAVI funding by August 2010.'*⁶

Request

The Board is asked to decide from among the three options listed above: 1) full reallocation of funds, 2) partial funding of the Indian programme and partial reallocation, or 3) leave the India programme as it stands.

⁴ GAVI/2010/052/RK/at

⁵ Letter received by Executive Office on 19 May 2010

⁶ Letter received by Executive Office on 8 June 2010