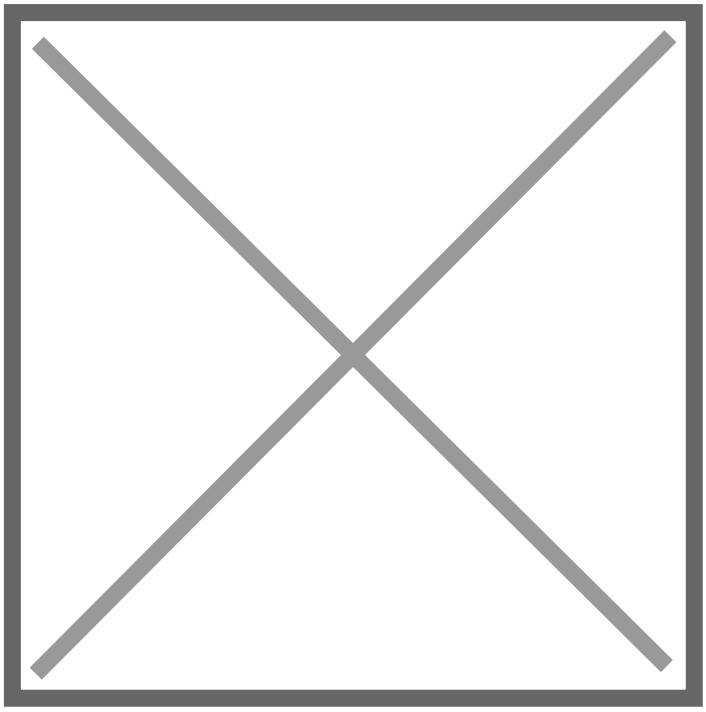
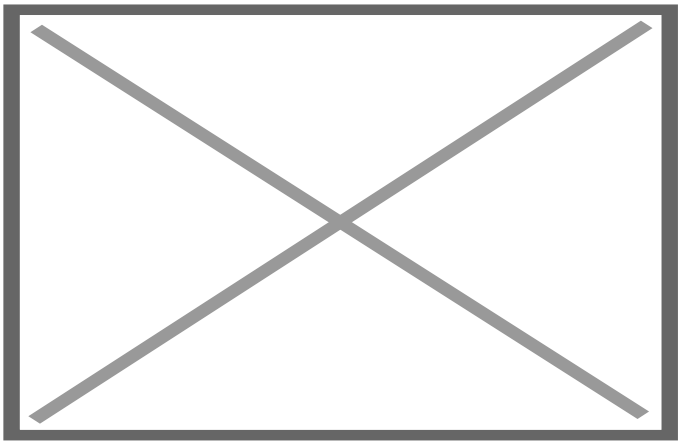
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Pentavalent vaccines: A new era in immunization

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In a move that would change the history of immunization in India, the Central government has started administering pentavalent vaccine in place of the existing DPT vaccine in a phased manner in Kerala and in Tamil Nadu. *BioSpectrum* explores the current scenario in the midst of doubts about the need for the pentavalent vaccine

On December 14, 2011, a two-and-half-month-old baby was administered the first pentavalent vaccine as part of the Universal Immunization Programme (UIP) in India. The event marked a change in the Indian government's policy on vaccines. The inclusion of pentavalent vaccine would replace the existing trivalent DPT (diphtheria, pertussis, tetanus) with a new vaccine that will offer immunity against hepatitis B and haemophilus influenza Type B apart from the three mentioned above.

After the World Health Organization (WHO) recommended that pentavalent vaccine be administered to every child in the world, the Government of India asked the National Technical Advisory Group on Immunization (NTAGI) to study the need for HepB and Hib vaccines in the Indian population. The NTAGI, in response, submitted a report in July 2008 recommending the introduction of Hib vaccine in all states as early as feasible and to adopt it under the UIP.

The NTAGI report quoted the studies carried out in India that reported case fatality rates of Hib meningitis to be 20-29 percent, while all invasive Hib diseases (including meningitis) have a fatality rate of 16 percent. The NTAGI recommended the use of Hib vaccine as it has the potential to prevent over 70,000 deaths of children below five years of age.

Ms Mahima Datla, senior vice president, Biological E, Hyderabad, which is the largest supplier of the DPT vaccines to the government, welcomes the government's move. Ã¢â?¬Å?The introduction of the pentavalent vaccine is a step in the right direction and clearly shows the government's commitment towards improving healthcare. The use of the pentavalent vaccine is a natural evolution from the DPT. However, we as vaccine manufacturers need more visibility of government decisions, as it would ensure that we are better prepared to fulfill the requirements,Ã¢â?¬? she says.

Experts also cite the phenomena of herd immunity having a strong impact in the case for Hib vaccinations, by which immunizing the majority of the population would reduce the disease risk in the unimmunized population.

Speaking about the advantages of their pentavalent vaccine COMVAC5, Dr Krishna Ella, CMD, Bharat Biotech, Hyderabad, states, Ã¢â?¬Å?The pentavalent formulation has several advantages as it halves the number of injections per child and

reduces the requirement of cold chain storage space besides easing management of logistics and data. With COMVAC5, Bharat Biotech has achieved a 10 percent market share in the India market and globally, a share of five percent.Ã¢â?¬? He adds that Bharat Biotech has devised strategies to further increase its market share to 25 percent in India and 15 percent globally.

Cost matters

Cost remains one of the most crucial factors that cannot be ignored while introducing an immunization drive for a large country like India. Currently, Global Alliance for Vaccine Initiatives (GAVI) is supplying pentavalent vaccines free-of-cost to India for a period of three years. The vaccine supplied by GAVI is the one manufactured by Serum Institute of India (SII) under the name Pentavac.

Ms AurÃ?Â©lia Nguyen, director of policy, GAVI Alliance, outlines the plan GAVI has for India. Ã¢â?¬Å?GAVI will be funding the vaccine in two states, Kerala and Tamil Nadu, throughout 2012, which will be more than 6.2 million doses. The roll-out of the pentavalent vaccine, which began in these two states last December, has reached over 100,000 children so far. India will be expected to share the cost of introduction of the pentavalent in 2012 by funding the procurement of auto-disposable syringes and waste disposal materials in addition to the delivery costs.Ã¢â?¬?

GAVI is working with the Indian government to explore how it can extend its support and set a program of work customized to India's priorities. The DPT costs the government 2.50 per dose, whereas the pentavalent vaccine was made available by Serum Institute to GAVI at the cost of 100 per dose. The latter's price, though much more than the cost of DPT vaccine, has dropped since the first year of its introduction. It was then purchased at the price of $3 per dose.

Ms Nguyen says the latest prices for Pentavac are yet to be published, which as the trends suggest could be lower than those procured earlier. However, the fact remains that in the next few years, the Indian government will gradually have to start footing the bill for pentavalent vaccines.

Is it needed?

There is also a debate on the need for such a vaccine. Dr Jacob Puliyel, department of paediatrics, St Stephens Hospital, Delhi, points out the concerns of many in the medical community who are questioning the need for this vaccine.

Ã¢â?¬Å?There remains to be a study that can give a scientific justification for the introduction of the Hib vaccine. The NTAGI committee has ignored data that show incidences of pneumonia are less than those projected by UNICEF. The deaths associated with the use of the vaccine in other countries also cannot be denied. There is an urgent need for active surveillance of the effects of the vaccine, which is currently lacking. The combination vaccines should not act as a back door entry for vaccines that we don't actually need,Ã¢â?¬? says Dr Puliyel.

Not all's well with vaccine makers

UNICEF, being the world's largest procurer of vaccines, acquires vaccines from the companies that have been prequalified by the WHO. Since Indian vaccine makers are said to supply over 50 percent of the world's requirements of vaccines, getting the prequalification approval is of utmost importance. In recent times, however, the prequalification approvals of a number of Indian companies have been revoked, due to non-compliance of WHO's regulations.

With respect to pentavalent vaccines, one of the first companies to face such a ban was Shantha Biotechnics. In 2010, the WHO, after withdrawing the prequalification approval, ordered the recall and destruction of all stocks of Shan5 on finding the presence of a white sediment on the walls of the vaccine vials. Dr Harish Iyer, CEO, Shantha Biotechnics, says Shantha has since then worked towards making the necessary changes to get prequalification to start producing Shan5 and bring it back to the market.

In August 2011, Panacea Biotec, which was among the first companies to launch a pentavalent vaccine EasyFive, faced similar circumstances when their prequalification approval was withdrawn due to inadequate quality assurance processes. The statement by the WHO states EasyFive was not found to be unsafe, but procurement would be stopped until the manufacturer implemented corrective measures.

Challenges ahead

Kerala and Tamil Nadu have reportedly been chosen as the first states to receive the pentavalent vaccines, keeping in mind their good track record with vaccination coverage. However, pentavalent vaccines were previously introduced in 2008 in various districts of Goa by the state government.

While the emphasis on preventable medicine is a positive step by the Government of India, its commitment will be tested in the coming years when it will have to make a concerted effort, like the one made for the polio immunization drive, to ensure

successful implementation. To begin with, it means a steady supply of these vaccines through joint efforts of both private and public sectors and high quality vaccines at affordable prices are required.

Manasi Vaidya in Bangalore