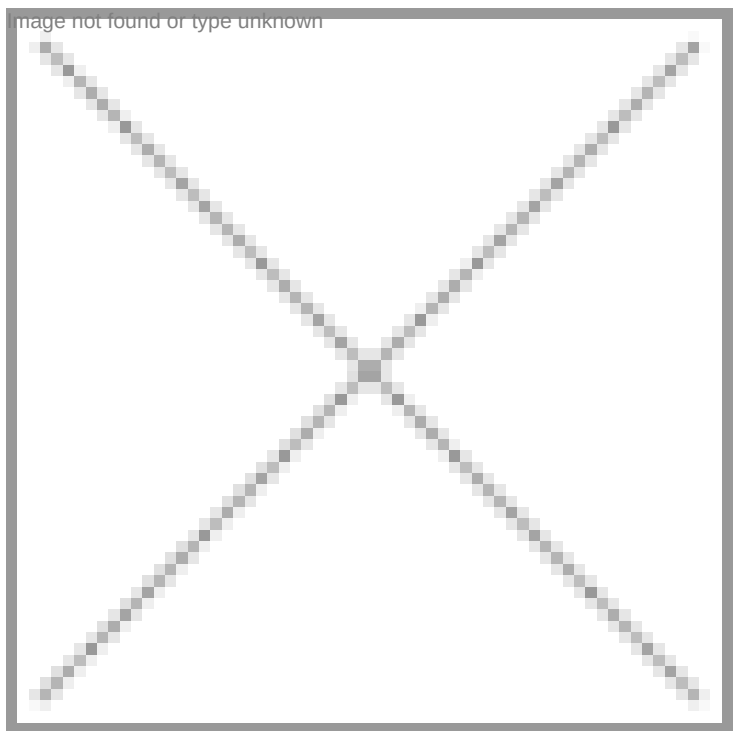
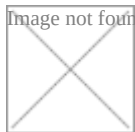


PUBLIC SECTOR VACCINE MANUFACTURING 2.0

11 May 2012 | News



The Cabinet Committee on Economic Affairs has given its approval to the proposal of the Ministry of Health and Family Welfare for establishment of an Integrated Vaccine Complex (IVC) at Chengalpattu in the Kanchipuram district of Tamil Nadu. Will this decision change the future of the public sector vaccine units?



The union government on January 15, 2008, suspended manufacturing licences of three public sector vaccine manufacturing units - Central Research Institute (CRI), Kasauli; Bacillus Calmette-Guérin Vaccine Laboratory (BCGVL), Guindy; and Pasteur Institute of India (PII), Coonoor, on account of noncompliance of good manufacturing practices (GMP) norms.

The various parliamentary standing committees on health slammed the health ministry for failing to take enough steps to restart the manufacture of vaccines in the three major public sector vaccine manufacturing units and hence raising the costs of the Universal Immunization Programme (UIP). The committee chaired by former health secretary Javed Chowdhary in its February 2010 report had urged an immediate restart of manufacturing by them in public interest. The government on February 26, 2010, in exercise of its powers under sub rules (3) of rule 85 of the drugs and cosmetics rules, 1945, ordered revocation of suspension of the licences of these sick vaccine institutes. The units have now been reopened for manufacturing by the health ministry.

Revival path

The Union Minister for Health and Family Welfare, Ghulam Nabi Azad, recently stated in the Parliament on the fresh funding infused into the sick units. He informed that the Union Government has given an approval to upgrade the vaccine

manufacturing facilities at BCGVL and PII at an estimated cost of ₹64.72 crore and ₹149.16 crore, respectively.

After a brief lull, around 134.55 lakh doses of Diphtheria, Pertussis, and Tetanus (DPT) vaccine have been produced in CRI Kasauli since the revocation of suspension of license in February 2010. The Pasteur Institute of India in the Nilgiris is all set to release its first set of anti-rabies vaccines in the market in June 2012. Sources aware about the future plans told *BioSpectrum* that about 39.5 million doses of DPT vaccines will be released in a year starting from June 2012. The third unit BCGVL, Chennai, is still to commence its manufacturing activities. Hence, the BCG vaccine, which protects against tuberculosis, is being supplied by the Serum Institute of India (SII), Pune. All the three units have also been asked to ensure that the production line is made fully compliant with GMP standards within three years.

Reasons for failure

Most of the non-governmental organizations (NGOs) in health area believe that the failure of the public sector units should be attributed to the failure of the government policies that ignored the requirement of the public sector units over an extended period of time. According to them, vaccine policies are increasingly shaped by industry's supply push. Vibha Varshney, science editor, *Down to Earth magazine*, observes, "It is interesting that the policy, which has been made in response to a Public Interest Litigation (PIL) asking for revival of public sector units, has so little to say about their revival. The policy accepts that India does not have the capacity to manufacture new vaccine to justify the involvement of the private sector. Why shouldn't there be efforts to increase the capacity of these PSUs?"

Culprits behind sickness?

- Poor patronage and policy support to public sector
- Frequent changes in production profiles
- Unfashionable under liberalization and globalization
- Routine production pressures
- Obsolescence of R&D infrastructure and receding emphasis on R&D
- Excessive dependence abroad
- Rigidities in recruitment and promotions
- Poor linkages, institutional mechanisms
- Governmental neglect of GMP

Interestingly, most of the industry experts also share a similar opinion. According to Krishna Ella, president, Vaccine Manufacturers Association of India that represents the top vaccine manufacturers such as Bharat Biotech, Biological E, Panacea Biotech, Serum Institute of India and Shantha Biotechnics, "The suspension or closure of vaccine manufacturing by the public sector vaccine manufacturers was perhaps due to lack of developmental planning in upgrading the facilities and equipment, inadequate compliance to GMP, lacunae in management practices and non-availability of suitable directors to

"By reopening and rejuvenating the public sector vaccine manufacturing units, the government may realize the vital importance of encouraging and sustaining the vaccine manufacturers to provide good quality vaccines that would meet international standards,"

The Cabinet Committee on Economic Affairs recently gave its approval to the proposal of the Ministry of Health and Family Welfare for establishment of an Integrated Vaccine Complex (IVC) at Chengalpattu in the Kanchipuram district of Tamil Nadu. The complex will be established by HLL Life Care, a public sector undertaking of the Ministry at an estimated cost of 594 crore. The project is likely to be completed by 2014. The news comes close on the heels of the government's recent directive for the upgradation of existing vaccine

The complex shall be the nodal center for research, manufacture and supply of vaccines under the UIP and are to be made available at affordable prices. The vaccines to be manufactured in the IVC include the pentavalent combination (DPT plus Hep B plus Hib). This move could be vital to fulfill the requirements following the government's plans for the inclusion of pentavalent vaccines in the UIP in December last year. Started initially in Tamil Nadu and Kerala, the program has

now been expanded to include six more states. The center will also be involved in the manufacturing of BCG, measles, Hepatitis B, Human Rabies, Hib and Japanese Encephalitis vaccines.

Revived PSUs

- Central Research Institute (CRI), Kasauli
- Bacillus Calmette-Guérin (BCG) Vaccine Laboratory, Guindy
- Pasteur Institute of India (PII), Coonoor

The annual capacity of IVC is expected to be around 585 million doses. The vaccines manufactured in the IVC complex are proposed to meet about 75 percent of the total requirement of vaccines covered under the UIP and shall be able to meet the requirements of the major disease

"The total project cost of IVC is 594 crore, of which 28 crore has already been released. We have also started on-site preliminary works

at the 100 acre area. Project office has started functioning with sufficient staff including the project officer," says HLL

The project has been started to provide vaccine security and consequently the health security of the nation. Vaccines produced in the complex shall be utilized for immunization of pregnant women, infants and small children against various diseases throughout the country.

After Suspension

A peep into unfolding of events from the date the PSUs were suspended to now

- Jan 2008: DCGI ordered suspension of vaccine production in CRI, PII and BCGVL on non-compliance of GMP
- July 2008: Appointment of expert committee on the future of vaccine PSUs
- Feb 2009: Supreme Court issues notice to the Union Government in the vaccine PIL
- June 2009: Health ministry prepares an action plan to revive PSUs by 30 June 2010
- Aug 2009: Government invests additional 14 crore to make CRI GMP-compliant
- Sept 2009: Government constitutes Javed Chowdhury Committee on vaccine PSUs
- Feb 2010: Health ministry sends revival orders to three PSUs
- April 2010: High Court issues interim order to the government to formulate a national vaccine policy
- Aug 2010: 43rd report of the Parliamentary Standing Committee on Health raps government
- Sept 2010: Final Report of Javed Chowdhury committee severely indicts government on PSUs
- Sept 2011: 52nd report of the Parliamentary Standing Committee on Health still critical
- April 2011: MOHFW released government's National Vaccine Policy, announced in July
- Nov 2011: High Court interim order to relook into government's vaccine policy document
- March 2012: Government says it has already approved a 213.88 crore package for upgradation of existing set up of BCG VL, Guindy and PII Coonoor.

The strong argument given in support of PSUs is that their existence is strategical as they are supposed to act as a buffer in times of medical emergencies. The supplies from government units can be faster than private players, claim those in support of their revival. The industry welcomed the government move and has come forward to help the government, though they were not consulted on these matters. Several industry leaders believe that there is still a lot of mistrust about private

Did the shortage of vaccines supply from the private sector prompt the government to revive the vaccine units? The industry experts refuse to believe so. KV Balasubramaniam, managing director, Indian Immunologicals (II), Hyderabad, denies by saying, "Shortage of vaccines is a thing of the past. That happened some years ago when the department units were suddenly closed due to GMP issues. They were not given time to modernize and improve. Our entry bridged a substantial part of that gap. This is a fact that has not been adequately acknowledged. We now meet a bulk of the requirements of DPT, TT and Hep B vaccines to the UIP programme. We had to discontinue measles vaccine due to issues with the way the vaccine was getting mixed up with diluents causing serious adverse events. The situation

Agreeing with him, Ella points out, "The apparent shortage of vaccines, if any, from the private manufacturers was due to the lack of advance planning by the government to procure vaccines from them. Indian vaccine manufacturers also supply vaccines to the private trade in other countries and also to the United Nations Children's Fund (UNICEF) and Global Alliance for Vaccines and Immunization

Many say that there is also a misconception on the price situation. The general belief in the industry is that the prices went up not because of shortage of the vaccines, but the demands of higher levels of quality compliance and the need to incorporate vaccine vial monitors (VVMs). VVMs are said to be the single biggest component of cost sourced from a monopoly WHO approved supplier outside India. The other argument is that manufacturers have to also account for inflation and a

depreciating rupee.

"There is now sufficient capacity in the country for the UIP vaccines and you are not hearing about shortages. There are sufficient number of manufacturers for almost all the UIP vaccines, except the measles vaccine where there is just one manufacturer. Notwithstanding this, there is definitely a case for reopening the units with good GMP in place to provide vaccine supply security," says Balasubramaniam.

Apprehensive future!

Integrated Vaccine Complex to come up in Tamil Nadu

- Integrated Vaccine Complex (IVC) to be established at Chengalpattu, Kanchipuram

district, Tamil Nadu

- HLL Life Care to set up the facility at an estimated cost of 594 crore
- HLL Lifecare floats subsidiary arm
- The project is likely to be completed by 2014
- The complex is planned to be the nodal center for research, manufacture and supply of UIP vaccines to be made available at affordable prices
- The vaccines to be manufactured in the IVC include the pentavalent combination (DPT plus Hep B plus Hib)
- The annual capacity of IVC is expected to be around 585 million doses and accounts for 75 percent of the total requirement of vaccines covered under the UIP
- In the first phase, IVC will have capacity to produce 100 million doses each of pentavalent, measles, Hib, and BCG vaccines. It will also have capacity for 140 million doses of Hep B, 20 million doses of human rabies, and 25 million doses of JE vaccines
- It will have a WHO-prequalified facility, the first-of-its-kind in the public sector, to manufacture futuristic meningococcal, rotaviral, dengue and pneumococcal vaccines in its multibacterial and multiviral facilities to meet any epidemic or pandemic situations
- IVC also seeks to develop a strong R&D base, apart from manufacturing and supplying 75 percent of the vaccines required for the UIP
- The central government has also entrusted HLL with the task of revamping BCGVL, PII, Coonoor, and CRI.
- HLL aims to be a 10,000-crore company by 2020

The future of these units still hangs in balance as they rely heavily on government support. Most believe that these units must be completely autonomous and free to take decisions on pricing and important issues pertaining to their growth. Balasubramaniam believes that the functioning of three units looked like that of production units of the Ministry of Health and not PSUs. He says, "Were they to be PSUs, the performance would have been much better. There is a case to reopen them in the interest of supply security but they have to be run as PSUs, given sufficient autonomy, managed well and earn enough to

Rahul Koul in New Delhi