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The National Vaccine Policy One Year After

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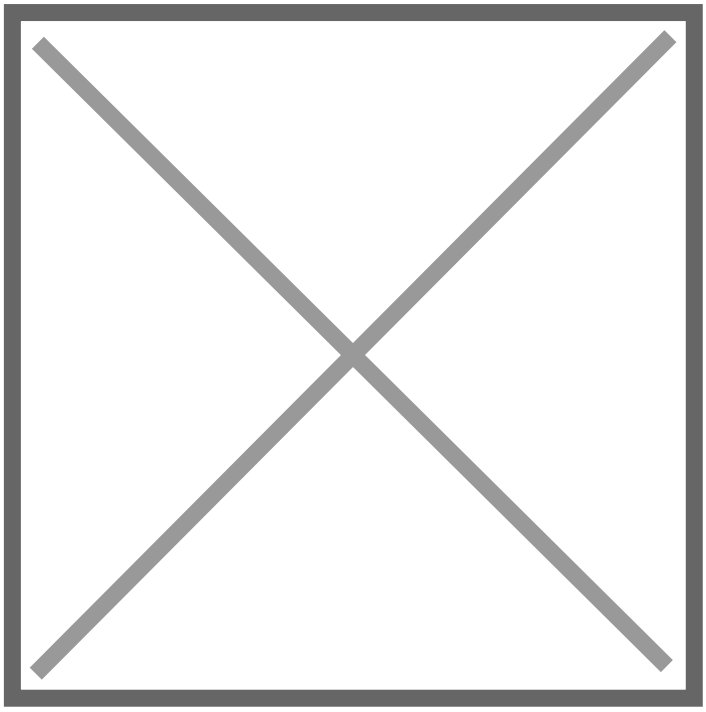

In an effort to provide detailed guidelines for formulating the vaccine strategies, the National Vaccine Policy was drafted and released in April 2011. BioSpectrum spoke to the industry to seek suggestions to strengthen the vaccine industry and the immunization program in India.

In what was perceived to be a move highlighting the Indian government's commitment to strengthen the vaccine outreach in India, NK Ganguly, former director general, Indian Council for Medical Research (ICMR), drafted the National Vaccine Policy that was released by the Ministry of Health and Family Welfare in April 2011. Now almost a year later, the policy remains largely a reference guide for the adoption of new vaccines and formulating the vaccine strategies in India. In a nation of one billion plus population, a comprehensive report to highlight the present bottlenecks in the procurement and administration of vaccines under the Universal Immunization Program (UIP) and others is needed, a point that was highlighted by National Technical Advisory Group on Immunization (NTAGI) on whose recommendation the policy was framed.
At a public forum last year, union health minister Ghulam Nabi Azad had highlighted the importance of the document by saying, Ã¢â?¬Å?The framing of the National Vaccine Policy has been a major step. This policy will now guide the immunization program in the country.Ã¢â?¬?

The intent of the policy document, now adopted by Government of India, seeks Ã¢â?¬Å?to develop a long-term plan to strengthen the whole vaccine program and intends to provide broader policy guidelines and framework to guide the creation of evidence base to justify the need for R&D, production, procurement, and quality assessment of vaccines for UIP in India.Ã¢â?¬?

A glaring disparity in the state of immunization in our country is the fact that even though Indian manufacturers supply over 43 percent of the global vaccine requirements, the average of national coverage of the essential UIP vaccines in India is below 50 percent. The UIP in India targets 2.7 crore infants with a domestic market of 100 million doses making it one of the largest in the world. The policy describes the current circumstances in the following way: Ã¢â?¬Å?The regular production and supply of vaccines under UIP, where majority of manufacturers are increasingly paying attention to the newer vaccines, is a big challenge. There is limited production capacity of these vaccines in public sector units and the involvement of private sector manufacturers is required to ensure that the supply of UIP vaccines is not threatened.Ã¢â?¬?

With this statement, the draft policy points out the significance of the vaccine industry, but underlies the need for active Public Sector Units (PSUs), lest UIP vaccines that are cheaper and less profitable are ignored by the industry.

Mahima Datla, senior vice president, Biological E, says, Ã¢â?¬Å?Each of the five top vaccine companies in India has the capacity to produce the required amount of UIP vaccines, so I do not think there is any capacity bottleneck.Ã¢â?¬?

Further in the draft policy a need to Ã¢â?¬Å?revive the PSUsÃ¢â?¬? and make them more Ã¢â?¬Å?competitiveÃ¢â?¬? is also expressed so that the supply of UIP vaccines is not threatened. The document however, does not give any detailed plans

for reviving the PSUs.

Whether it be public or private sector units, the adherence to the required standards of quality is a necessity in a sensitive area such as vaccines. The successful revival of the PSUs that were closed on similar accounts, thus hinges on the presence of a strong National Regulatory Authority that can oversee the adherence of the Good Manufacturing Practices (GMP) standards of the units. The policy calls for an authority that is focused only on vaccines, as an alternative to the current situation in which the the Central Drugs and Standards Control Organization (CDSCO) headed by the Drugs Controller General of India (DCGI) is the National Regulatory Authority (NRA). The presence of such a body would not only allow for faster approvals, but also ensure that the quality of the proceedings is maintained for public as well as private units.

14 Point Plan to Success

- Link geographical Information System with UIP network to track delivery of vaccines
- Use National Polio Surveillance Project (NPSP) as a reference point for successful programs
- Address the lack of indigenous surveillance data to assess the disease burden
- Map vaccine R&D activities to avoid duplication of efforts
- Encourage PPPs through flexible governing and grants
- Draft India-specific standard operating procedures for biorepositories which can aid in vaccine and diagnostics research
- Provide industry a channel to voice its opinion
- Develop prequalification approval standards aligned with WHO standards
- Single window system to avoid regulatory delays
- Set up system to fast track vaccines needed for emergencies
- Revive vaccine PSUs and make the units competitive
- Let NTAGI have wider representation by including experts from public health, pediatrics, and those working in epidemiology and infectious-disease areas
- Upgrade Central Drug Laboratory at Kasauli to get NABL certification
- Have a clear coordination between state and center for vaccine adoption

Nata Menabde, World Health Organization (WHO) representative to India, says, Ã¢â?¬Å?In 2009, Indian authorities had lost the right to issue approvals and they regained it the next year after much difficulty. In 2012, this will be very crucial given the fact that recently WHO has declassifed three manufacturers that the national body had given approvals, which raised questions about if the authority can do proper justice to the licensing procedures. Without proper license of the licensing authority you cannot have the credibility regarding your vaccines. It is very shameful to see different standards for vaccines for domestic use and export purpose.Ã¢â?¬?

Industry reacts

Krishna Ella, CMD, Bharat Biotech and president, Vaccine Manufacturers Association, India, is welcoming the policy wholeheartedly and says, Ã¢â?¬Å?I would like to emphasize that India did not have a national vaccine policy for several decades and now we have it. It is essential to continue with the Public Private Partnership (PPP) to sustain the leadership of the Indian vaccine manufacturers in the global arena.Ã¢â?¬?

KV Balasubramaniam, MD, Indian Immunologicals, Hyderabad, while appreciating the policy document pointed out, Ã¢â?¬Å?In my view, what we need first is an 'Immunization Policy' which states the policies and priorities with respect to immunization in India to meet the preventive health challenges where vaccines are just one part. My stress is equally on priorities along with policies. How do we reduce the unacceptably high level of AEFIs, adverse events following vaccination? These issues need to be addressed too.Ã¢â?¬?

The vaccine industry, which is unique in the fact that in most cases its single largest customer is the government itself, is lauded in the policy for its PPP initiatives for newer vaccines. However, industry insiders are of the opinion that there is a need to further involve the industry in the decision making process to ensure the supply needs of the government can be met in a timely manner.

The National Vaccine Policy of India is meant to be a document that can explain the way forward for immunization in our country. As Ella puts it, Ã¢â?¬Å?It is now up to the ministries of health and family welfare of the central and state governments, the NTAGI, the medical profession in general and the paediatricians in particular to add strength to the National Vaccine Policy.Ã¢â?¬?

The National Vaccine Policy describes all the steps that need to be taken to improve the immunization process in India. However, now that the Ã¢â?¬Å?whatÃ¢â?¬? has been defined, the Ã¢â?¬Å?howÃ¢â?¬? needs to be formulated. A more thorough goal-based planning based on the guidelines given in the policy document can be conducted to be able to deliver on it and make the policy actionable.

Manasi Vaidya in Bangalore