

## India gets WHO approval for vaccine exports

15 January 2013 | Features

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A World Health Organization (WHO) team consisting of 16 experts from different nationalities have assessed the vaccine clearance procedures of the Indian Central Drugs Standard Control Organization (CDSCO) and NRA (National Regulatory Authority) and found them to be "stringent enough and (that) the international community can be assured that vaccines produced by Indian companies are of high quality, safe and efficacious." The NRA adhered to the six critical control functions laid out by WHO, thus receiving the official accreditation from the public health agency.

The stamp of approval from the WHO for the country's regulatory body comes as a welcome move, not just because it helps open up doors to Rest Of the World (ROW) markets and international aid agencies for Indian manufacturers, but also because it helps clear India's image in terms of quality of vaccines that had taken a beating in recent times. The WHO approval also holds special meaning, since India has failed the same audit which was previously carried out in 2009, not once but on three separate occasions in the past. It would also make India the first country to pass the current required norms. The Drug Controller General of India (DCGI) explicitly stated that, had Indian failed to meet the necessary criteria, it would have had to stop the export of its vaccines to over 159 countries. The audit team however concluded that more could be done in the areas of pharmacovigilance and reporting of adverse events following vaccination.

Currently, India's vaccine exports include primary ones such as those for diphtheria, pertussis and tetanus, of which India caters to 80 percent of the world's supply as well as other comparatively advanced ones such as those for hepatitis, meningitis and the pentavalent vaccines. Companies manufacture 30 different types of vaccines for domestic as well as the international use.

On receiving the approval, the Drug Controller General of India, Dr GN Singh said, "We have passed with flying colors. India has become the first country to pass the stringent indicators put in place by the WHO, in one shot. WHO has also assured us of their help in capacity building on drug regulation in India. The team has expressed total confidence in the quality of Indian vaccines being exported to all corners of the world."

A WHO endorsement remains crucial since international aid agencies such as GAVI (Global Alliance for Vaccines and Immunization), WHO and UN (United Nations) aid agencies all source their vaccine subjects to a WHO prequalification approval. Experts also hope that a WHO approval for the country's regulatory body can have far reaching implications, that might result in domestic manufacturers also adhering to the highest standards in quality. Dr Harish Iyer, CEO, Shantha Biotechnics says, "This move is very positive as it confirms that Indian vaccine manufacturers will continue to play a major role in the procurement of United Nations Agencies and emerging countries in general."

WHO approvals and those of the national agencies such as NRA hold special significance. Dr Satish D Ravetkar, executive director, Serum Institute of India, said, "WHO audits are an ongoing exercise at Serum Institute, specific to each vaccine that we manufacture. Due to our robust quality systems that are ingrained in the DNA of the company, we do not face any problems." Serum Institute of India is the largest vaccine company in India, and over 80 percent of the global vaccines requirement are catered by it.

Dr Harish Iyer, echoes the importance of exports by saying, "Exports featured highly in Shantha's case, with more than three quarters of our revenues in 2012 coming from exports. We have conducted a quality, safety and immunogenicity development plan, including manufacturing, regulatory and clinical aspects, designed to strongly improve the robustness of the processes used by Shantha in the past few years as well."

"In the last four years, the government has been under pressure after WHO cracked down on the government and some of the private units for lack of quality, safety and efficacious issues. The steps taken by the government during this period like capacity building, strengthening of manpower (regulators), e-governance system to increase transparency and credibility, stringent monitoring system, consumer awareness programs, up gradation of existing central drugs laboratories and conduct regular overseas inspections to verify GMP compliance and other statutory requirements and many other initiatives helped the WHO team to give green signal for the export of Indian vaccines. Now it is time for the Indian vaccine industry to maintain the status without compromising on quality, safety and efficacy of life saving vaccines by following transparency and ethical practices," opined Mr KV Balasubramaniam, managing director, Indian Immunologicals.

### **Exports set; What about India?**

According to a recently released report by McKinsey - Organization of Pharmaceutical Producers of India (OPPI), in 2012, close to 2 million Indians, mainly children, died from diseases that could have been prevented by vaccines. Also alarming is the fact that according to data from the Ministry of Health and Family Welfare, the immunization budget for routine immunization as well as the pulse polio program has in fact reduced from 5.5 percent of the healthcare budget in 2010-11 to 4.7 percent in 2011-12.

The report also mentioned that the Indian vaccines market remains under-penetrated for several reasons such as lack of awareness or ability to purchase the vaccine. But this scenario could change. Over the next decade, the Indian vaccines market has the potential to substantially increase the number of lives saved by improving access to different types of vaccines available and the depth of coverage of those vaccines across the country.

The report also suggested that government and pharmaceutical companies can stimulate the expansion of vaccines in India through a number of actions, notably reducing complexity in the Universal Immunization Program (UIP) process, increasing the prescriber base, improving sales and marketing and investing in delivery and supply. The stakeholders such as government and industry need to play a crucial role in realizing this transformation to counter the significant mortality crisis associated with a small and under-penetrated vaccines market. Sustained, progressive and collaborative efforts by the industry and policy makers can make this potential a reality.

As Indian units gear up to supply life saving vaccines to the rest of the world, a thought to ponder is, how long will it be before the Indian population can reap the benefits of its scientific and technological prowess.