World Health Organization
COUNTRY OFFICE FOR India

National Regulatory Authority of India meets WHO international standards for vaccine regulations

New Delhi, 17 February 2017: The National Regulatory Authority of India (NRA) and affiliated institutions meet the WHO Global Benchmarking Tool requirements for a functional vaccine regulatory system.

A World Health Organization (WHO) led team of international experts from several countries came to this conclusion at the end of a comprehensive review from 13-17 February 2017.

"This is indeed a great achievement and we would like to congratulate the Ministry of Health & Family Welfare and its affiliated institutions: Central Drugs Standards Control Organization (CDSCO); Central Drugs Laboratory, Kasauli; Pharmacovigilance Programme and Immunization Division, and other relevant institutions engaged in the regulation, control and testing of vaccines," said Dr Alireza Khadem, WHO Team Leader for the NRA Re-benchmarking, Group Lead, Regulatory System Strengthening Team.

Speaking about this landmark development, Mr C.K. Mishra, Secretary Health, Health & Family Welfare, Government of India said that the Central Drugs Standards Control Organization, in collaboration with WHO, has made exemplary efforts towards this achievement.

"India is one of the largest manufacturers and exporters of vaccines world-wide; this development further deepens our resolve to maintain the highest quality and efficacy of the products that are manufactured within our country and in this context, we look forward to strengthening our collaboration with WHO," he added.

Welcoming the positive outcome of international assessment, Dr Henk Bekedam, WHO Representative to India said, "It will go a long way in re-affirming India's role in global health, including the strength of its pharmaceutical sector and drug regulatory capacity."

"WHO had scaled up its technical support to the India's national regulatory authority over the past several years. This success is a culmination of intensive effort by the Health Ministry, including CDSCO, in collaboration with WHO, to implement a roadmap to strengthen capacity for regulation of vaccines. WHO will continue to support development of the NRA through technical advice, training and capacity building," he added.

One of the requirements to become eligible and retain the prequalification status is to have the NRA assessed as functional against the WHO Global Benchmarking Tool. Safety, efficacy and quality are three basic parameters of assessment of vaccines. WHO has established global standards and benchmarks for assurance of vaccine quality by development of tools and guidelines, benchmarking of the NRA and Prequalification programme of vaccines.

In addition to the general framework for the system, the following regulatory functions were evaluated: registration and marketing authorization; licensing of premises; vigilance; market surveillance and control; lab access and lot release by the national regulatory authority; regulatory inspections; and oversight of clinical trials.

The WHO Prequalification Programme (PQP) is aimed at facilitating access to vaccines that meet unified standards of quality, safety and efficacy as well as programme needs. It is also prerequisite for manufacturers to supply to countries through United Nations procuring agencies.

A functional NRA is a criterion for WHO prequalification of vaccines.

India is a major vaccine producer that has 21 major vaccine manufacturing facilities. These vaccines are used for the national and international market (150 countries), which makes India a major vaccine supplier across the globe.

India continues to meet the standards of the WHO NRA published indicators (WHO Global benchmarking Tool) on functional regulatory system for vaccines. This allows the domestic vaccine manufacturers to apply for WHO vaccine prequalification. It also allows export of Indian vaccines to the world immunization market, and will probably lead to more affordable vaccines. As for all NRA benchmarkings, sustainability of the gains made in regulatory capacity is critical.

For this purpose, the team, which has just completed the assessment in India, has drawn up a detailed Institutional Development Plan. The plan will outline additional activities to be undertaken to further strengthen regulatory capacity in India in the coming years.

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