



Ministry of Health and Family Welfare

# High Standards of Vaccine Regulation

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A WHO team comprising experts with decades of experience in different areas of Regulatory Systems in Regulatory Agencies, Laboratories and Institutes from WHO Hqrs, WHO India office, USA, Italy, Germany, the Netherlands, Indonesia, Thailand and Egypt has carried out a comprehensive assessment of India's National Regulatory Authority.

Indian Vaccine Regulatory System was assessed by WHO against Global Benchmarking Tool (GBT) comprising 9 functions for measuring the maturity of Indian Vaccine Regulatory System viz. National Regulatory System; Registration & Marketing Authorization; Vigilance; Market Surveillance & Control; Licensing Premises; Regulatory Inspections; Laboratory Access & Testing; Clinical Trial Oversight; and NRA Lot Release. WHO has given highest possible rating of 4 in five functions viz. Registration & Marketing Authorization; Vigilance; Laboratory Access & Testing; Clinical Trial Oversight; and NRA Lot Release. WHO has given a rating of 3 in respect of the remaining four functions.

Indian National Regulatory Agency has been declared functional by WHO based on the most comprehensive assessment ever carried out by WHO anywhere in the world with 63 indicators and 288 sub-indicators.

The Minister of State (Health and Family Welfare), ShFaggan Singh Kulaste stated this in a written reply in the Rajya Sabha here today.

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