



Ministry of Health and Family Welfare

# Vaccination in India

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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 to 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.

The assessment was carried out by a WHO team comprising experts with decades of experience in different areas of Regulatory Systems in Regulatory Agencies, Laboratories & Institutes from WHO Hqrs, WHO India office, USA, Italy, Germany, Netherland, Indonesia, Thailand and Egypt.

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), Sh Faggan Singh Kulaste stated this in a written reply in the Lok Sabha here today.

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