

## PRESS RELEASE

### Maximum Possible Marks to Indian NRA in WHO Assessment

WHO has completed the assessment of the status of the Indian vaccine regulatory system against WHO NRA Global Benchmarking Tool (GBT) for benchmarking and measured the maturity of the system. The assessment has been carried out by a WHO team comprising lead experts in different areas from WHO Hqrs., Geneva, WHO India Country Office, experts drawn from the regulators of USA, Italy, Germany, Netherlands, Indonesia, Thailand and Egypt. The assessment has been done in respect of nine different functionalities and Indian NRA has been declared 'functional' with a maturity level of 4 *i.e.* the highest level as per currently evolved definitions in respect of 5 functions, and maturity level 3 in respect of 4 functions. While, maturity level 4 indicates good results and sustained improvement trends, maturity level 3 reflects systematic process based approach, early stage of systematic improvements, data availability regarding conformance to objectives and existence of improvement trends.

India is one of the main players in the pharmaceutical industry worldwide. The pharmaceutical industry covers conventional as well as biological medicinal products including vaccines, medical devices, and traditional medicines. India, as a large vaccine producing country, is currently supplying several vaccines to the UN agencies (UNICEF, WHO and PAHO).

A fully functional NRA is a pre-requisite for WHO prequalification of vaccines. One of the requirements to become eligible and retain prequalification status is to have the National Regulatory Authority (NRA) assessed as functional against the WHO published NRA indicators. WHO Prequalification Programme, as such, facilitates access to vaccines that meet the unified standards of quality, safety and efficacy as well as programme needs. The vaccine manufacturers can only apply for WHO vaccine prequalification if the NRA meets the standards of the WHO NRA published indicators *i.e.* WHO Global benchmarking Tool on functional regulatory system for vaccines.

World Health Organisation (WHO) has, based on a robust benchmarking tool developed over years in consultation with various experts drawn from across the globe, carried out assessment of the National Regulatory Authority (NRA) of India comprising the Central Drugs Standard Control Organisation (CDSCO), State Drug Regulatory Authorities, Pharmaco-vigilance Programme of India (PvPI) and Adverse Events Following Immunization (AEFI) structures at the Central and States levels. The nine functions included in the tool are National Regulatory System; Registration and Marketing Authorization; Vigilance; Laboratory Access and Testing; Regulatory Inspection; Clinical Trial Oversight; NRA Lot Release; Licensing Premises; and Market Surveillance and Control. The Global Benchmarking Tool (GBT) so developed has 63 indicators and 288 sub-indicators, out of which 150 are critical with the following maturity level definitions:

The result reflects the growing maturity of the Indian NRA emanating from a concerted effort by the Government in consultation WHO to build capacity and capability of the National Regulatory Authority over last several years.

