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In reply please
refer to:

Your reference:

H.E. Mr J.P. Nadda
Minister of Health and Family Welfare
Government of India
Nirman Bhawan, Maulana Azad Road
New Delhi,
India

20 February 2017

Excellency,

Congratulations to Your Excellency and the Ministry of Health for a very successful outcome of the WHO conducted assessment of the National Regulatory Authority (NRA) of India from 13-17 February 2017.

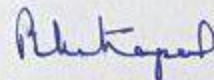
As Your Excellency is aware, WHO promotes equitable access to quality, safe, efficacious, and affordable medical products and health products by supporting countries in strengthening their regulatory systems. For this purpose, a team of WHO led international experts covered the assessment of National Regulatory Authority (NRA) in India, comprising of the Central Drugs Standard Control Organisation (CDSCO), State Drug Regulatory Authorities, Pharmacovigilance Programme of India (PvPI) and Adverse Events Following Immunization (AEFI) structures at the Central and States levels. 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.

The previous WHO assessment (benchmarking) of the Indian vaccine regulatory system was conducted in 2012 during which institutional development plan (IDP) and the road map for strengthening the NRA were developed. The present team of WHO-led team of international experts reported a 100% compliance which is another landmark achievement.

India being one of the main suppliers of medical products worldwide, manufactures drugs and biological medicinal products including vaccines, medical devices, and traditional medicines and is supplying several vaccines to UN agencies. The successful assessment will go a long way in strengthening global confidence in medical products from India and also give an impetus to the 'Make in India' mantra of the Hon'ble Prime Minister of India.

Congratulations once again and I hope we will achieve more milestones in the months ahead.

Please accept, Excellency, the assurances of my highest consideration.



Dr Poonam Khetrapal Singh
Regional Director