

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:2747
ANSWERED ON:09.12.2011
SETTING UP NHRDA
Sugavanam Shri E.G.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has any proposal to set up National Health Regulatory and Development Authority (NHRDA);
- (b) if so, the details alongwith proposed functions thereof;
- (c) whether the proposed Authority would also regulate pharmaceuticals and medical devices; and
- (d) if so, the details thereof?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a): The Planning Commission had set up a High Level Expert Group (HLEG) on Universal Health Coverage for India, in October 2010. In their Report, HLEG has recommended for setting up National Health Regulatory and Development Authority (NHRDA). The recommendations of HLEG are under consideration of Planning Commission.

(b): HLEG has recommended for the three following units under NHRDA :

i) The System Support Unit (SSU), responsible for developing standard treatment guidelines, management protocols, and quality assurance methods for the UHC system. It would be responsible for developing the legal, financial and regulatory norms as well as the Management Information System (MIS) for the UHC system. ii) National Health and Medical Facilities Accreditation Unit (NHMFACU), which would be responsible for the mandatory accreditation of all allopathic and AYUSH health care providers in both public and private sectors as well as for all health and medical facilities. iii) The Health System Evaluation Unit (HSEU), which would be responsible for independently evaluating the performance of both public and private health services at all levels – after establishing systems to get real time data for performance monitoring of inputs, outputs and outcomes.

(c) & (d): No. The HLEG has recommended for setting up National Drug Regulatory and Development Authority (NDRDA) to regulate pharmaceuticals and medical devices and provide patient access to safe and cost effective products.