

**GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA**

UNSTARRED QUESTION NO:2379
ANSWERED ON:08.12.2011
EVALUATION OF LABORATORIES
Rai Shri Prem Das

Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

- (a) whether the Government has set any standards to evaluate the working of the laboratories that test vaccines in the country;
- (b) if so, the details thereof;
- (c) whether these laboratories are able to meet the international standards;
- (d) if so, the details thereof; and
- (e) the steps being taken by the Government in this regard?

Answer

MINISTER OF STATE IN THE MINISTRY OF PLANNING; MINISTER OF STATE IN THE MINISTRY OF SCIENCE AND TECHNOLOGY AND MINISTER OF STATE IN THE MINISTRY OF EARTH SCIENCES (ASHWANI KUMAR)

(a) The Government has set standards to evaluate the working of laboratories in the country that test vaccines in addition to testing of chemicals and other Biologics through National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation & Good Laboratory Practice (GLP) certification. NABL accreditation is a formal recognition of the technical competence of a testing, calibration or medical laboratory for a specific task following ISO/IEC 17025:2005, ISO 15189:2007 Standards. The GLP certification is provided by the National Good Laboratory Practice Compliance Monitoring Authority (NGCMA), Department of Science and Technology to pre-clinical testing laboratories conforming to the OECD (Organization for Economic Cooperation and Development) Principles of Good laboratory Practices and OECD Council Acts.

(b) NABL accreditation to laboratories ensures reliable testing and calibration services that enhances customer confidence in accepting reports issued by accredited laboratories. NABL Accreditation is currently given for testing, calibration and medical laboratories to include Biological, Chemical and other fields. Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. The scope of the GLP principles include chemical entities & biologicals used in Pharmaceuticals, agrochemicals, industrial chemicals, veterinary chemicals, food & feed additives, cosmetics and nutraceuticals. The validity of the GLP certificate for a laboratory is three years. The NABL accreditation & GLP certification are presently voluntary and not a pre-requisite for submission of data to Regulatory Authorities before registration of a new product.

(c)&(d): NABL is signatory to APLAC (Asia Pacific Laboratory Accreditation Cooperation) MRA (Mutual Recognition Arrangement) and ILAC (International Laboratory Accreditation Cooperation) MRA since 2000. NABL has valid accreditation of 1526 laboratories in 2539 fields/subfields as on November, 2011. India was invited to join the OECD's Working Group on GLP as a full member on March 3, 2011. This implies that data generated in a GLP certified facility in India would now be acceptable in all OECD member countries and other adherent countries. Presently there are 18 GLP certified laboratories all of them meet international standards of OECD Principles of GLP.

(e) The Department of Science and Technology is proactively trying to encourage advancement of NABL and GLP in the country by putting in place enabling steps to encourage laboratories in both Government and Private sector to reach international standards. These include imparting trainings to assessors/inspectors, sensitization and training programmes for laboratories, quality assurance personnel & study directors with an aim to encourage quality systems in the country.