

**GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY**

**LOK SABHA
UNSTARRED QUESTION NO. 484
TO BE ANSWERED ON 06/02/2019**

EVALUATION OF LABORATORIES

**484. SHRI DHANANJAY MAHADIK :
DR. HEENA VIJAYKUMAR GAVIT :
DR. J. JAYAVARDHAN :
SHRI MOHITE PATIL VIJAYSINH SHANKARRAO :
SHRI SATAV RAJEEV :
SHRIMATI SUPRIYA SULE :**

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 other steps being taken by the Government in this regard?

ANSWER

MINISTER OF SCIENCE & TECHNOLOGY AND EARTH SCIENCES; ENVIRONMENT, FOREST AND CLIMATE CHANGE

(DR. HARSH VARDHAN)

(a to e) Yes Madam, National Accreditation Board for Testing and Calibration Laboratories (NABL) is a Constituent Board of Quality Council of India. NABL has been established with the objective of providing Government, Industry Associations and Industry in general with a scheme of Conformity Assessment Body's accreditation which involves third-party assessment of the technical competence of testing including medical and calibration laboratories, proficiency testing providers and reference material producers. Accreditation program is voluntary in nature.

NABL provides accreditation in all major fields of Science and Engineering such as Biological, Chemical covering various scopes like Drugs, Food, Water, Pollution etc. The laboratory accreditation services to testing and calibration laboratories are provided in accordance with ISO/ IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories. NABL accreditation system also takes note of the requirements of Mutual Recognition Arrangements (MRAs) of which NABL is a member.

NABL accredits laboratory based on test and test methods , laboratories seeking accreditation are assessed and their compliance to International Standard ISO/IEC 17025 :General Requirements for the Competence of Testing and Calibration Laboratories is ensured. The laboratories accredited by NABL for Vaccines are Central Research Institute, Kasauli; Enterovirus Research Centre (Indian Council of Medical Research), Mumbai and the National Institute of Biologicals, Noida.

The National Good Laboratory Practice Compliance Monitoring Authority (NGCMA) has also been set up under the administrative control of the Department of Science and Technology (DST) to award GLP certification to test facilities conducting pre-clinical testing of chemicals (viz. Pharmaceuticals, Industrial Chemicals, Pesticides, Veterinary Drugs, Cosmetics, Food Additives, Feed additives, etc.) in accordance with Organization for Economic Cooperation and Development (OECD) Principles of GLP. NGCMA has certified 47 test facilities in the country whose data is mutually accepted by 36 OECD member countries in accordance with Mutual Acceptance of Data (MAD) agreement.
