

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

UNSTARRED QUESTION NO:1536
ANSWERED ON:13.12.2013
COMMITTEE ON APPROVAL OF DRUGS
Kalmadi Shri Suresh

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

- (a) whether the Government has proposed/put in place any mechanism to ascertain the efficacy and safety of foreign certified drugs and equipment in local conditions before issuing licence for their sale in the country;
- (b) if so, the details thereof and the monitoring mechanism proposed/devised for the purpose;
- (c) whether the expert committee constituted under the chairmanship of Prof. Ranjit Roy Chaudhury on approval of new drugs has since submitted its report;
- (d) if so, the details thereof indicating the details of the major recommendations made by the committee; and
- (e) the follow up action taken/proposed by the Government thereon?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a)&(b): Approvals of New drugs are granted under the Rules 122 A, 122 B, 122 DA, 122 DAA, 122 DAB, 122 DAC, 122 DB, 122 DD and Schedule-Y of Drugs and Cosmetics Rules, 1945. The Schedule -Y provides detailed guidelines and requirements to ascertain the efficacy and safety of new drugs in local conditions before the grant of approval for their marketing in the country.

(c)to(e) :Yes. The salient recommendations of the committee include.

1. Establishing a system for accreditation of clinical trial Investigators, Ethics Committee and Clinical Trial Sites,
2. Establishing technical review committees for clinical evaluation of applications of new drugs by the office of Drugs Controller General (India) [DCG (I)].
3. Guidelines for Post Marketing Surveillance (Phase- IV trials) for monitoring of safety of drugs in post marketing scenario,
4. Review of continued marketing of drug formulations available in the country by the Independent Expert Committee

Detailed recommendations of the Committee alongwith action that the Government has decided to take thereon have been uploaded on the website of Central Drugs Standard Control Organization (CDSCO) i.e. www.cdsco.nic.in.