

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

STARRED QUESTION NO:415
ANSWERED ON:24.08.2005
COMMITTEE FOR APPROVAL OF NEW DRUGS
Mehta Shri Alok Kumar

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

- (a) whether any Committee has been constituted for the approval of new drugs;
- (b) if so, the details thereof; and
- (c) the details of terms and reference of the Committee and the number of new drugs approved by the Committee since its inception?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a)to(c): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 415 FOR 24TH AUGUST, 2005

A Standing Committee of experts under the Chairmanship of DG, ICMR, was constituted on 17.01.2001 for Investigational New Drugs (IND). The Committee examines Investigational New Drugs indigenously discovered in the country and gives recommendations to Drugs Controller General (I) for grant of permission to conduct various stages of clinical trials before the drug is approved for manufacture and marketing.

The terms and conditions of the Committee are as under:

(i) To undertake indepth evaluation of data furnished by the applicant for an Investigational New Drug (IND) or New Chemical Entity (NCE). These are the molecules/products, which have never been earlier tested in human beings. The data would include the chemistry of drug substance, animal toxicological study reports etc. relating to safety, metabolism of drugs as well as the proposed Phase I study protocol.

(ii) To advise the DCG(I) in matters relating to regulatory provisions under Schedule Y of the Drugs and Cosmetics Rules and any modifications required thereof.

There are about 21 INDs currently undergoing various stages of clinical trials. However, none of these new drug molecules have passed the Phase III stage of clinical trial. New drugs approval for marketing purpose is considered only after Phase III clinical Trial data submitted by the applicant.