GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:877
ANSWERED ON:27.02.2015
APPROVAL OF APPLICATIONS FOR CLINICAL TRIALS
Adsul Shri Anandrao ;Mani Shri Jose K.;Patil Shri Shivaji Adhalrao;Reddy Shri Ponguleti Srinivasa;Yadav Shri Dharmendra;Yeddyurappa Shri B. S.

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

(a) the number of clinical trials of drugs/ vaccines presently being hosted by the country;

(b) whether the drug manufacturing industry has witnessed a slowdown on account of stringent/ unfavourable provisions relating to clinical trial and pharmaceutical products approval mechanism;

(c) if so, the details thereof indicating the number of applications for conduct of clinical trials of drugs/vaccines received indicating the number out of them approved during each of the last three years and the current year;

(d) whether the Government proposes to put in place a regulatory pathway to enable technical deliberations between the drug regulator and stakeholders to address concerns before the companies make formal application seeking product approvals or permission for clinical trails, and if so, the details thereof; and

(e) the other measures being taken by the Government for speedy approval of applications for clinical trials?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): The number of applications received for seeking Clinical Trials approval and cases where permission has been granted during last three years and the current year is as below:

Year	No. of Applications	Permissions granted #
2012	480	253
2013	207	73
2014	230	198
2015 (up to 17.02.2015)	17	27

This includes permissions granted for applications received in the previous years.

(b): The clinical trials are conducted in respect of new drugs which does not impact manufacturing of drugs in any significant manner.

(c): The details are indicated in reply to part (a) above.

(d): Central Drugs Standard Control Organization (CDSCO) has placed a scheme regarding pre-submission meeting between CDSCO and applicants on its website.

(e): The Government has already included a large number of experts in the Subject Expert Committees. With this, the time-frame for processing of Clinical Trial appli- cations has been reduced substantially.