GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:1589 ANSWERED ON:15.07.2009 CLINICAL TRIAL REGISTRY Mahtab Shri Bhartruhari

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

- (a) whether the Clinical Trial Registry is freely available to the public;
- (b) if so, the details thereof;
- (c) whether all trials are being registered;
- (d) if so, the number of trials registered in the Registry during the last three years and the current year;
- (e) whether any discrepancies in the outcomes of trial protocols and published reports have been noticed by the Government; and
- (f) if so, the corrective measures taken by the Government in this regard?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

- (a) & (b): Clinical Trial Registry- India (CTRI), maintained by National Institute of Medical Statistics, Indian Council of Medical Research (ICMR), is a free online registry of clinical trials at www.ctri.in.
- (c): Currently all interventional trials are being registered in the CTRI. Observational and Bioavailability/Bioequivalence trials are not currently being registered. Trial Registration has been made mandatory with effect from 15th June 2009.
- (d): The CTRI was launched on the 20th of July 2007. As of 13th July 2009, 338 trials have been registered.

During July 2007 to December 2007, 11 trials were registered.

During January 2008 to December 2008, 137 trials were registered.

During January 2009 to July 2009, 190 trials were registered.

(e) & (f): The Central Drugs Standard Control Organisation (CDSCO) under Ministry of Health & Family Welfare has not received report of any such discrepancies in the outcomes of trial protocols and published reports.