

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

UNSTARRED QUESTION NO:2064

ANSWERED ON:31.07.2015

Clinical Trials on HIV Drugs

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

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

- (a) whether the World Health Organisation (WHO) has pointed out critical lapses in trials of HIV drugs being conducted by a Chennai-based research organisation in the country, and if so, the details thereof;
- (b) whether the Government has conducted any investigation in this regard;
- (c) if so, the details and the outcome thereof along with the action taken/ proposed by the Government thereon; and
- (d) the steps being taken by the Government to tighten regulations on ongoing clinical trials of drugs in the country?

**Answer**

- (a): As per reports published in the media, the World Health Organisation (WHO) has issued a Notice of Concern to M/s. Quest Life Sciences Pvt. Ltd., Chennai about critical lapses in a trial relating to HIV drugs including the fact the two third electrocardiograms (ECGs) could be duplicate.
- (b) & (c): The Central Drugs Standards Control Organisation (CDSCO) has constituted a Committee on 10.07.2015 to investigate the matter.
- (d): Adequate provisions have been made in the Drugs and Cosmetics Rules, 1945 to ensure ethical conduct of Clinical Trials.