GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:846
ANSWERED ON:25.02.2011
QUALITY OF IMPORTED DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether clinical trials of drugs imported from abroad including China have been conducted in the country before allowing their marketing;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether the Comptroller and Auditor General of India (CAG) has found any discrepancies in batch release certification for products of Chinese Pharmacopoeia in the year 2009;

(d) if so, the details thereof alongwith the action taken thereon; and

(e) the fresh measures taken/proposed for proper compliance of procedures to ensure the quality of drugs imported in the country?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) & (b) Cases of new drugs proposed to be introduced for the first time in the country are requested to be approved by DCG (I)as per the laid down procedure under the Drugs and Cosmetics Act and the regulations Rules thereunder which include conduct clinical trials also. Further the Drugs imported from other countries, including from China, are subjected to random testing to check their quality.

(c)& (d) In its report on Performance Audit of National Institute of Biologicals for the year ended March 2008, the Comptroller & Auditor General of India (CAG) observed that the Institute had issued batch release certification for certain products of Chinese origin without complying with the mandatory parameters. Disciplinary action was initiated against the then Director of the Institute and he has since been repatriated to his parent Department. The procedures have since been fineturned so as to prevent recurrence of such incidents. These include steps to test the biological products by the parameters specified in the pharmacopoeia/ other guidelines and protocols, proper documentation, streamlining of procurement of essential reagents and supplies, placing equipment under annual maintenance contract and perkiodical calibration.

(e) The following decisions/measures have been taken to ensure quality of drugs imported into the country:

1. Approval of the scheme for site inspection by the Central Drugs Standard Control Organisation (CDSCO) of firms in foreign countries includes China exporting drugs to India to ensure that the drugs are manufactured as per prescribed standards and Good Manufacturing Practices.

2. Fresh guidelines have been put in place. The documents submitted at the time of registration are subjected to scrutiny and if considered necessary, regulatory body of the exporting country e.g. the State Food Drug Administration (China) is requested to confirm the authenticity of the document submitted.

3. Testing of the drugs at the time of registration and random testing are done by Port Officers to check the quality of drugs imported into the country.