GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:122
ANSWERED ON:23.11.2005
SALE OF SUB STANDARD MEDICINES
Mandal Shri Sanat Kumar

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

(a) Whether sub-standard medicines in the country are being sold and the Drug Controller has failed to curb their sale;

(b) If so, the reasons therefore;

(c) Whether there is any inadequacy in the Drugs Control Organizations (DCOs) at the Central and State level;

(d) If so, the details thereof; and

(e) The steps taken/ proposed to be taken by the Government in this regard?

Answer

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

(a) to (e): Quality of drug in the country is monitored by the respective State Drugs Controlling Authorities by way of random sampling of drug products from markets as well as other distribution points. The colleted samples are analyzed by the Govt. AnalystS at various Central and State Drugs Testing Laboratories. As per the information available from the State Drugs Control Departments, the following are the results arising from such samples:

Year	No. of sample tested	No. of Drugs declared not of standard quality
2001-2002	38,824	3458
2002-2003	43, 138	3724
2003-2004	40,862	3499
2004-2005	49,287	3695

A drug is considered not of standard quality or substandard if it fails to comply with any of the parameters as laid down by recognized pharmacopoeia or by the manufacturer. Substandard drugs can result due to inadequate pre formulation development studies or lack of in-process controls exercised by the manufacturers during the process of manufacturing. The drug preparationS may also be declared substandard if they are not stored or transported under proper condition. It is pertinent to mention that a substandard drug may or may not be a harmful drug. Drugs may be declared substandard because of defects which may not affect the therapeutic efficacy of the drug.

As the State Drug Inspectors draw samples of drugs, hence action on the substandard test reports are taken by the State Drug Control Authorities. Normally administrative actions against the manufacturer are taken by way of warnings, suspension, or cancellation of licence when the defects observed are not of serious nature. However, in case of substandard drugs due to serious defects, prosecution in the Court of Law is also instituted by the State Drugs Inspectors.

Due to paucity of funds and other infrastructure of State Drug Testing Laboratories, number of samples drawn for tests is limited. A Capacity Building Project through World Bank assistance has been taken up to provide substantial assistance to State Govts. to upgrade drug testing facilities and in some instances to establish new drug testing laboratories. It is expected to increase the number

of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months.