THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Application for import of rDNA biotech drugs are examined as perthe provision made under Drugs & Cosmetics Act and Rules thereunder. In respect of imported rDNA biotech drugs for which marketing approval is sought, the decision regarding Phase III clinical trial is taken based on the available information in respect of regulatory status of product, published data on safety, quality efficacy and end use of the drugs marketing authorization, other country's approval etc.

Unlike other pharmaceuticals, rDNA biotech drugs also require approval of Genetic Engineering Approval Committee (GEAC), as per the rules framed under the Environment Protection (EP) Act, 1986, of the Ministry of Environment and Forests, for its safe release of drugs into environment.

(c) and (d) The following imported rDNA biotech drugs have been indentified for conducting Phase III clinical trial in the country:

1. r Human insulin Glulisine APIDRA inj.,

2. r Human Granulocytes colony stimulating factor inj.,

3. r Human Erythrpoietin inj.,

4.4l Human Interleukin IL3 inj.

Spurious drugs

†879. SHRI RAM JETHMALANI:
SHRI RAJ MOHINDER SINGH MAJITHA:

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

(a) whether Government's attention has been drawn to the Report of World Health Organisation (WHO) stating that 35 per cent of the spurious drugs produced in the world are being manufactured in India;

(b) if so, whether Government have gathered any facts in this regard; and

(c) if so, the details thereof and steps taken and proposed to be taken to curb this practice?

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†Original notice of the question was received in Hindi.

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKALAKSHMI): (a) There have been media reports quoting varying figures about the alleged extent of circulation of spurious drugs including a reference to a alleged WHO study that 35% world's spurious drugs are produced in India.

(b) The WHO, in writing, has denied having conducted any such study/ survey and having issued any such report that 35% of world's spurious drugs are produced in India.

(c) Under the Drugs and Cosmetics Act, 1940 and Rules framed thereunder, the State Government through their respective Drugs Control Organizations are empowered to regulate manufacture of drugs and to monitor the quality of drugs moving in the inter-State commerce.

As per the feedback available from the Drugs Controller of States/ UTs, 36947,38824,36314,39465 drug samples were attested during the period 2000-01,2001-02,2002-03 and 2003-04 out of which 112, 96,125 and 108 samples respectively were found spurious which is 0.3, 0.25, 0.34 and 0.27% of the samples reported spurious. Thus, it does not appear that the spurious medicines have been growing alarmingly.

Government of India has been taking various initiatives to ensure uniform and strict action to tackle the problem of spurious drugs. Some of such specific initiatives are as follows:

(i) Issues concerning alleged sale of spurious drugs taken up by Union Health Minister with State Health Ministers in the conference of Central Council of Health and Family Welfare.

(ii) Meeting of State Drug Controllers together with representatives of pharma industry and trade organizations, arranged.

(iii) Financial assistance provided to State for augmentation of drug testing facilities.

(iv) Matter concerning sale of spurious drugs and initiatives to be taken up by State Governments were taken up by Union Health Minister with all Chief Ministers in October, 2002.

(v) A World Bank assisted Capacity Building Project on Food Safety and Quality Control of Drugs has been launched with effect from October, 2003. This project aims at strengthening, *inter-alia,* the

drug regulatory infrastructure in the country by augmenting the drug testing facilities by providing for equipments, civil works, staff and consumables and extensive training of drug regulatory/quality control officials and industry personnel. Annual drug testing capacity to be raised to 1,00,000 samples as against 36,000 to 38,000 samples.

(vi) Special training programme for improving investigations and legal skills organized for State officials.

A legislation to amend the penal provisions of Drugs and Cosmetics Act, 1940, and to provide for stricter penalties to the offenders including a maximum penalty of capital punishments, was introduced in the Parliament in December, 2003.

Since the Bill has now lapsed with the dissolution of previous Lok Sabha, necessary action to introduce a Bill to enhance penalties for manufacture and/or sale of spurious and/or adulterated drugs under the Drugs and Cosmetics Act, 1940, has been initiated by the Ministry of Health and Family Welfare.

Revision in prices of drugs

880. SHRI M.A.M. RAMASWAMY: Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is a fact that the National Pharmaceutical Pricing Authority made a downward revision in the prices of certain drugs;

(b) if so, the details of drugs whose prices were revised by the NPPA including the earlier prevalent prices of these drugs;

(c) whether it is also a fact that most of the pharmaceutical companies are still selling these drugs on the pre-revised rates;

(d) if so, the names of such companies; and

(e) the action taken against such companies by the Central Government?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI RAM VILAS PASWAN): (a) to (e) In accordance with the provisions of the Drugs