(h) the names of the investigators who conducted the trials of this combination alongwith the details of each report;

(i) whether it is a fact that this combination was cleared by the state drug authorities; and

(j) if so, the name of the authority and the justification for granting permission ?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR) : (a) to (j) Licences for manufacture and sale of formulations are granted by the State Drug Control Authorities, the combination of Ibuprofen and Dextropropoxyphene has been licensed to be manufactured and marketed by the State Drug Control Authorities. As per information available with this Ministry combination of Ibu-profen and Dextropropoxyphene has been licensed for manufacture and sale by the Commissioner Food and Drug Administration, Maharashtra State, to M/s. Wokhardt Pharmaceuticals, Bombay and to M/s. DWD, Bombay and by the Drugs Controller, Himachal Pradesh to M/s. Shivchem Pharmaceuticals Simla. The Drugs Controller, Andhra Pradesh had informed that one firm by name M/s. Ambuja Laboratories, Hyderabad has been permitted to manufacture the combination of Ibuprofen and Dextropropoxyphene but the said firm has latter suspended the manufacture of the said product.

The Commissioner, Food and Drug Administration, Maharashtra State, had informed, that the said combination had been approved by him in consultation with the Professor of Pharmacology, Grant Medical College, Bombay who was apparently of the view that the combination had therapeutic rational.

To the best of our knowledge the combination of Ibuprofen and Dextropropoxyphene is not being marketed anywhere else in the world.

Dangerous effects of Baralgen

1708. SHRI NAND KISHORE BHATT : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether it is a fact that Baralgen tablets and injections are being marketed in India;

(b) whether it is a fact that a number of published reports indicating dangerous effects by use of these products have come in various medical journals and bulletins in the world ;

(c) whether it is also a fact that health authorities of most of the developed countries like U.K., Australia, Japan, Sweden etc. have already withdrawn these products from their markets ; and

(d) if die reply to parts (b) and (c) above be in the affirmative what are the reasons for not withdrawing this drug in India ?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR) : (a) Yes, Sir.

(b) and (c) Reports had appeared regarding the problem of agranulocytosis i.e. fall in the number of granulocyte cells in the blood. This adverse reaction to the drug is allergic in nature and can occur in patients with a specific susceptibility to the drug. However, there is no unanimity of opinion in scientific circles regarding the extent of incidence of agranulocytosis as a result of the use of this drug. It is because of this that while certain countries have

banned the use of the drug, other countries have permitted its use. Analgin is the active ingredient of Baralgen.

To the best of our knowledg while preparations containing Ana'-gin are marketed in West Germany Maxico, Thailand, Japan, Italy, USSR, Spain, Brazil, Neitherland, Belgium, France, they are banned in Australia, U.K., U.S.A., Canada, Sweden and Denmark.

Analgin (Dipyrone), an active ingredient of Baralgen is an analgesic antipyretic drug and is used to alley different types of pain and also to lower down temperature. The drug is marketed in the country either alone or in combinations by both Indian and foreign firms. The drug Analgin is an official drug in U.S.S.R. Pharmacopoeia and also in the Indian Pharmacopoeia, (d) The question of banning the use of Analgin was examined by the Government in consultation with the Drugs Consultative Committee and the Drugs Technical Advisory Board. In view of the fact that this drug is currently being marketed in a number of developed countries and a detailed study of the adverse reaction of Analgin is being conducted by the Drug Epidemiology Unit of Bosten University, both the bodies had recommended that the question of banning may be considered after the results of this study are available. An interim report of the large scale Boston study which is still in progress has been made available to us. According to this study the reported low incidence of 5 cases of agranulocytosis per million (such incidence rate covering not Analigin alone but all drugs) have prompted the Ethical Committee of the Bosten Collaborative Group to recommend continuation of the study.

The question of banning the use of the drug Analgin would be considered after the final results of this study are made available to us.

Accident involving 153 Up Jayanti Janata and a truck

1709. SHRIMATI MAIMOONA SULTAN : SHRI RAMCHANDRA BHARADWAJ :

Will the Minister of TRANSPORT be pleased to state:

(a) whether it is a fact that the 153 Up Jayanti Janata Express collided with a truck at a railway level crossing in Muzaffarpur (Bihar) on the 15th February, 1986, in which at least three persons were killed;

(b) if so, what were the circusmtances and causes of the accident; and

(c) what action has been taken against those found responsible for the accident

THE MINISTER OF STATE IN THE DEPARTMENT OF RAILWAYS (SHRI MADHAV RAO SCINDIA) : (a) The accident occurred at an unmanned level crossing in which two persons were killed.

(b) Negligent driving by the truck driver, who tried to cross unmanned level crossing in the face of an approaching train.

(c) The truck driver, responsible for the accident, died on the spot due to which police could not take action against him for rash and negligent driving.

1710. [*Transferred to the 14th March 1986*]

दिल्ली-अलीगढ़ और मेरठ शटलों का समय

1711. श्री अच्छेलाल बाल्मीक : क्या **परिवहन** मंत्री यह बताने की कृपा करेंगे कि:

(क) क्या नई दिल्ली–अलीगढ़ शटल और नई दिल्ली–मेरठ शटल के समय में