GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 3750

TO BE ANSWERED ON THE 9TH August, 2016

Manufacturing of Amiloride HCI

3750. SHRIMATI BUTTA RENUKA:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether it is a fact that Amiloride Hydrochloride (HCl) 5mg tablet, a medicine that is included in the List of Essential Medicines prepared by the World Health Organisation (WHO), is being manufactured in the country;
- (b) if so, whether Amiloride HCl, helps in retaining potassium and magnesium in the human body and is approved for marketing in the country;
- (c) if so, the names of the companies that have obtained licence to market this medicine;
- (d) whether this medicine is currently being sold;
- (e) if not, the details of action proposed to be taken by the Government against the pharmaceutical companies that have obtained the licence, but are not selling the medicine; and
- (f) whether the Government is taking any measures to make this essential drug available to patients in the country in view of the fact that potassium and magnesium related potentially life-threatening conditions are increasingly becoming common?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

- (a): As per Pharma Trac database or IPDMS database, no manufacturer is seen to be manufacturing Amiloride HCI 5mg tablet.
- (b): In view of reply to (a) above, does not arise.
- (c): Amiloride HCI tablet was approved in India in September, 1979 for the treatment of oedema and hypertension to M/s MSD Pharmaceutical.

- (d): As per Pharma Trac database or IPDMS database, no manufacturer is seen to be manufacturing Amiloride HCI 5mg tablet.
- (e)&(f): National Pharmaceutical Pricing Authority (NPPA) has instructed concerned manufacturer to channelize the supply in domestic market and submit compliance report to NPPA.

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