

GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 1647
TO BE ANSWERED ON THE 6th March, 2018
WHO Approved Medicines

1647. SHRI P. NAGARAJAN:

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

- (a) whether it is true that the World Health Organisation (WHO) has recently approved the use of anti-diarrhoea vaccine produced by Indian Pharma major, Bharat Biotech Worldwide;
- (b) if so, the details thereof; and
- (c) the total number of medicines and vaccines produced by Indian pharma companies which have been approved by WHO for use worldwide, as on date?

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) & (b): The Department of Biotechnology (DBT) has informed that the rotaviral diarrhoea vaccine called ROTAVAC®; developed by an Indian company (M/s Bharat Biotech International Limited-BBIL), has been pre-qualified by WHO for procurement by public health vaccination programmes across the world.

(c): Under the Drugs and Cosmetics Act, 1940 and Rules made thereunder, license for manufacturing of drugs is granted by State Licensing Authorities appointed by respective State Governments. Central Drugs Standard Control Organization has granted Marketing Authorization for Rotavirus Vaccine to M/s Bharat Biotech International Limited, Hyderabad vide permission dated 03.09.2013 for the indication of active immunization of infants from the age of 6 weeks for the prevention of Gastroenteritis due to rotavirus infection. Central Drugs Standard Control Organization has informed that there is no information regarding medicines and vaccines produced by Indian Pharma companies which have been approved by WHO for use worldwide.

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