GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 786
TO BE ANSWERED ON THE 07TH FEBRUARY 2025

Production of Indigenous Antibiotic

786. Shri P P Chaudhary:

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

(a) the specific research and development efforts that led to the successful development of Nafithromycin, along with details of institutions and investments involved therein;
(b) whether any clinical trials have been conducted to establish Nafithromycin's effectiveness against resistant bacterial infections, if so, the findings thereof compared to existing antibiotics;
(c) whether any plan has been formulated for domestic production and pricing of Nafithromycin to ensure its affordability and accessibility, if so, the details thereof; and
(d) whether any assessment has been made regarding potential reduction in antibiotic imports through indigenous production of Nafithromycin, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) and (b): Nafithromycin has been developed by Wockhardt Group. The Phase III trial for this antibiotic was partly supported by the Biotechnology Industry Research Assistance Council (BIRAC), a public sector enterprise under the Department of Biotechnology. BIRAC committed financial support to the tune of Rs. 9.18 crore.

Based on non-clinical and clinical data including results of comparative clinical trial with Moxiflioxacin and the recommendations of the Subject Expert Committee (Investigational New Drugs), on 1st January 2025, Nafithromycin tablet 400 mg has been approved under the provisions of the New Drugs and Clinical Trials Rules, 2019 for manufacturing in the country for treatment of adults (above 18 years old) with community acquired bacterial pneumonia (CABP), for supply only to medical colleges, tertiary care hospitals or district hospitals.

Nafithromycin is a novel macrolide specifically designed for the treatment of CABP. It offers several key advantages in terms of effectiveness, safety and side-effect profile, particularly in addressing resistant bacterial infections, details of which are as under:

(i) *Effectiveness:* Nafithromycin has a broad spectrum of activity, making it effective against all major CABP pathogens. Its bactericidal activity, high lung penetration

and prolonged post-antibiotic effect ensure effective pathogen clearance and enable an ultra-short, three-day, once-daily dosing regimen, which improves patient compliance and outcomes.

(ii) *Safety and side effects:* Nafithromycin stands out as a safer option compared to other antibiotics. Unlike fluoroquinolones, which carry risks of severe side effects such as tendonitis, neuropathy and cardiac issues, Nafithromycin is well-tolerated across age groups, including elderly patients, the key population vulnerable to CABP. It does not need a combination drug treatment, providing a safer alternative therapy for CABP. Further, as an alternative to fluoroquinolones, Nafithromycin avoids concerns regarding selection of resistant *Mycobacterium tuberculosis* bacterial infections.

(c): As per the provisions of the Drugs and Cosmetics Act, 1940, manufacture of a drug is permissible only under and in accordance with conditions of a licence issued under the Act by the licensing authority. To promote the manufacture of pharmaceuticals in India, the Department of Pharmaceuticals is implementing the Production Linked Incentive (PLI) Scheme for Pharmaceuticals with total financial outlay of ₹15,000 crore with scheme tenure till the financial year 2027-28. Under the scheme, 55 selected applicants are eligible for production linked financial incentive for the manufacturing of identified products under various product categories, including patented drugs, for a period of six years. As a patented drug, Nafithromycin is eligible for incentives at the rate of 10% on sales made under the scheme.

The prices of drugs are regulated by the Drugs (Prices Control) Order, 2013, issued by the Government under the Essential Commodities Act, 1955, pursuant to the National Pharmaceuticals Pricing Policy, 2012. Under the said Order, the manufacturer of a non-scheduled formulation is at liberty to fix the maximum retail price of the formulation launched by it, subject to the stipulation that the manufacturer shall not increase the maximum retail price of the formulation by more than 10% during preceding 12 months. As a non-scheduled drug, the pricing of Nafithromycin is governed by the aforesaid provisions.

(d): No, sir.

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