GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 715
TO BE ANSWERED ON THE 07TH FEBRUARY 2025

Production of Nafithromycin

715. Shri Khagen Murmu:
Shri Chavda Vinod Lakhamshi:
Dr. Rajesh Mishra:
Shri Vishweshwar Hegde Kageri:
Shri Praveen Patel:
Shri Pratap Chandra Sarangi:
Shri Anurag Sharma:
Shri Balabhadra Majhi:

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

(a) the manner in which launch of Nafithromycin is aligned with India's long-term strategy to become self-reliant in the production of essential medicines and reduce dependence on imports;
(b) whether the Government is making any efforts to promote the production and distribution of Nafithromycin within the Country;
(c) if so, the details thereof; and
(d) the comparison between Nafithromycin and other antibiotics in terms of effectiveness, safety and side effects especially in the treatment of resistant bacterial infections?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a): 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. This is in line with India's vision of becoming Atmanirbhar.

(b) and (c): With the objective of enhancing India's manufacturing capabilities by increasing investment and production in the pharmaceutical sector, 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.

(d): 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.

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