GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA UNSTARRED QUESTION NO. 2709. TO BE ANSWERED ON 04TH AUGUST, 2023

PRICES OF 3RD AND 4TH GENERATION ANTIBIOTICS

2709: SHRI GURJEET SINGH AUJLA:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the Government is planning to reduce the prices of 3rd and 4th generation antibiotics mainly used after surgery thereby reducing the gap in Wholesale Landing price and MRP to control the Profit shared by doctors, hospital, pharmacists and agents and if so, the details thereof;
- (b) whether the Government is planning to subsidise the medicines used to treat chronic diseases like Diabetes, cardiac issues, kidney failure, liver failure and arthritis which are usually expensive and if so, the details thereof; and
- (c) whether the Government is planning to control/ regulate the practice by specialists who manufacture and control their own brands and its availability thereby fleecing the poor/customers and if so, the details thereof?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (DR. BHARATI PRAVIN PAWAR)

(a) & (b): The National List of Essential Medicines (NLEM) of the Ministry of Health & Family Welfare (MHFW) is incorporated in the Schedule-I of Drug Price Control Orders (DPCO), 2013. The formulations under Schedule-I of DPCO, 2013 are mentioned according to their therapeutic category.

There is no separate classification of antibiotics based on the generations i.e., 3rd or 4th generation Antibiotics. However, the Section 6.2 of Schedule I of DPCO, 2013 deals with the class, "Antibacterials", which includes 95 formulations of 27 medicines. Out of these, ceiling price for 74 formulations have been fixed under NLEM 2022 and 11 formulations under NLEM 2015 as on 31.07.2023.

The ceiling price of the medicines listed in Schedule - I is fixed by NPPA, and it includes the medicines used for the treatment of diabetes, cardiac issues, kidney diseases, liver failure and arthritis, for the purpose of price control.

The details of prices fixed by NPPA are available on the website of NPPA i.e., nppaindia.nic.in

(c): The safety, efficacy and quality of the medicines, whether branded or generic, imported or manufactured for sale, distribution in the country are required to comply to the same standard as specified in the Second Schedule of the Drugs and Cosmetics Act, 1940 and Rules.

Drugs and Cosmetics Rules, 1945 has been amended making it mandatory that the application for grant of license for a drug formulation containing single active ingredient shall be made only in proper name. Amendments have been made in the Drugs and Cosmetics Rules, 1945 for making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the Drug licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.
