

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 404
TO BE ANSWERED ON 06TH FEBRUARY, 2024**

CONTROL OF UNSCIENTIFIC COMBINATIONS OF DRUGS

404: SHRI S. SELVAGANABATHY:

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

(a) whether Government is aware that several unscientific combinations of drugs have flooded the markets as Fixed Dose Combinations (FDCs) and if so, the details thereof;

(b) whether the National Pharmaceutical Pricing Authority (NPPA) has raised some concerns on drug cocktails and has flagged the issue to the Indian Council of Medical Research (ICMR) and if so, the details thereof;

(c) the details of FDC drugs banned during the last three years;

(d) whether Government has taken any measures to fix the prices of new drugs which were FDC medicines or drug cocktails; and

(e) if so, the details thereof?

ANSWER

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

(a) to (c): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. Under the said Rules, Fixed Dose Combinations is a new Drug. For the manufacture of any FDC falling under the definition of New Drug, permission is required from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority.

Under the afore-said Act, manufacture/sale/distribution of any banned drug is a punishable offence. State Licensing Authorities are empowered to take action in this regard.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

The Central Government vide notifications dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution. It also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications dated 07.09.2018. Subsequently,

Central Government, vide notifications dated 11.01.2019, prohibited 80 FDCs for manufacture, sale or distribution. Further, Central Government vide notification S.O. 2394(E) to S.O. 2407(E) dated 02.06.2023 prohibited 14 FDCs for manufacture, sale or distribution. List of banned FDCs is available on the website of CDSCO i.e. www.cdsc.gov.in.

National Pharmaceutical Pricing Authority (NPPA), under the aegis of Department of Pharmaceuticals (DoP) flagged the issue of fixed dose combinations (FDCs) to Indian Council of Medical Research (ICMR) as detailed below:

"The Authority noted that the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. The Authority deliberated upon the matter in detail and expressed its concern that approval of these FDCs may compromise the rationale in the usage of the drugs and may lead to over medication. The Authority also apprehended that fixation of retail price of these FDCs may lead to a higher price being fixed than the sum of the price of their individual components resulting in profiteering by the companies. The Authority is of the view that guidelines in the usage of these FDCs needs to be looked into. Accordingly, the Authority requested that matter may be highlighted to Indian Council of Medical research (ICMR), New Delhi."

(d) & (e): NPPA fixes the retail prices of new drugs as defined in para 2(1)(u) of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) which includes FDCs also. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies and no manufacturer/retailer can sell the new drug above the notified price. NPPA has fixed retail prices of 2626 new drugs till 31.01.2024.
