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

**RAJYA SABHA**
**UNSTARRED QUESTION NO.1890**
**TO BE ANSWERED ON 02nd AUGUST, 2022**

## FIXED DOSE COMBINATION

**1890: 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 a legal regulatory framework has led to this situation in the country and if so, the reaction of Government thereto;

(c) 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; and

(d) the details of FDC drugs banned during the last three years?

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

(a) to (d) : The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules 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 Combination (FDC) is a new Drug. For the manufacture of any New Drug, permission is required from the Central Licensing Authority, before obtaining its manufacturing license from the concerned State Licensing Authority.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) by some of the State Licensing Authorities (SLAs) without due approval of the Central Licensing Authority came to the notice of the Government.

Advisories and reminders have been issued to the State/UTs Drug Controllers to withdraw or ban FDCs which are approved without the permission of CDSCO, under the provision of Drugs & Cosmetics Act, 1940 and Rules 1945.

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.

Department of Pharmaceuticals has informed that National Pharmaceutical Pricing Authority (NPPA) has also flagged to Indian Council of Medical Research (ICMR), New Delhi, the issues concerning the retail price applications of new drugs consisting of Fixed Dose Combinations (FDCs) and rationale in the usage of these drugs.

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