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Health ministry expert panel for banning 343 fixed drug combinations

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In December last year, the Supreme Court had directed the panel for a fresh review of safety, efficacy and therapeutic justification of 349 FDCs

AFTER REVIEWING 349 fixed drug combinations (FDCs), an expert panel of the health ministry on Wednesday recommended that 343 of them should be "prohibited" and the remaining six should be "restricted or regulated".

In December last year, the Supreme Court had directed the health ministry's expert body, Drugs Technical Advisory Board (DTAB), for a fresh review of safety, efficacy and therapeutic justification of these 349 FDCs. Therefore, the DTAB formed a sub-committee, which studied the issue and submitted its recommendations on Wednesday.

FDC means a combination of two or more drugs in a fixed dosage ratio. According to a senior government official, the expert sub-committee has clearly stated in its report that "for most FDCs, their use would lead to unnecessary overuse and the patients would be exposed to the risk of multiple ingredients when one would suffice".

The official added that according to panel, while 343 FDCs should be banned, "three FDCs should be restricted for specific indications or diseases", and other "three FDCs should be restricted to specific quantities of ingredients and for specific indications". Total 344 FDCs were banned on March 10, 2016, by the central government on the suggestion of the panel formed under the chairmanship of C K Kokate. Some that were banned were: Cefixime + Azithromycin, Ofloxacin + Ornidazole Suspension, and Metronidazole + Norfloxacin.

Kokate committee, which studied the irrationality of various FDCs, recommended the ban on 344 of them, citing the rising "antibiotic resistance" in the country as one of the reasons. Antibiotic resistance is the ability of a microorganism, which is causing the disease, to withstand the effects of an antibiotic medicine.

On December 1, 2016, Delhi High Court struck down the ban stating that the government had acted in a "haphazard manner". The matter then went to the Supreme Court, which stated in December last year: "In order that an analysis be made in greater depth, we, therefore, feel that these cases should go to the DTAB and/or a sub-committee formed by the DTAB for the purpose of having a relook into these cases."

The SC had stated that the DTAB or its subcommittee would have to decide whether it is "necessary in the larger public interest, to regulate, restrict or prohibit the manufacture, sale or distribution of such FDCs".