

F. No. FDC/7/2023-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan,
Kotla Road, New Delhi.

Date:

16 MAY 2024

To,

All State/UTs Drugs Controller,

Subject: DTAB Sub-Committee to examine the proposal to regulate antibiotic and its irrational use -Reg.

This is with reference to the meeting of the expert group held on 25.04.2023 at ICMR HQ, New Delhi on pathway for strategic access to new antibiotics and regulation against excessive and irrational use of antibiotic in India. One of the recommendations of the expert group was to take steps that inappropriate combinations being sold currently should be banned immediately and steps should be taken that the inappropriate combinations do not find their way to India markets in future.

Subsequently, a meeting was held under chairmanship of Dr. Atul Goel, DGHS on 16.10.2023 to discuss how to regulate antibiotics overuse and irrational use. The committee has decided that CDSCO will be responsible for 6 monthly review of various fixed drug combinations of antibiotics marketed in various states.

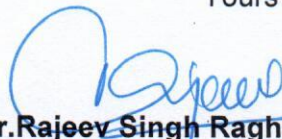
Further, the proposal was placed in the 90th DTAB meeting held on 25.01.2024 wherein the committee deliberated the matter and a sub-committee constituted under chairmanship of Dr. D.S Arya to examine the matter in detail and give their recommendation vide O.M no F.No. 15-05/2024-DC dated 08.04.2024.

In this regard, the first meeting of Sub-Committee was held on 01.05.2024 through Webex wherein the following actions were recommended:

- 1) Request SLAs to provide the list of antibiotic combinations licensed by them for manufacturing and marketing in their respective states.
- 2) Request SLAs to monitor the availability of unapproved antibiotic combinations if any, moving in the market under their jurisdiction and intimate CDSCO on priority.

In view of above, you are requested to provide the list of antibiotic combinations licensed by you till date within 2 weeks. You are also requested to monitor the availability of unapproved antibiotic combinations if any moving in the market under your jurisdiction and take necessary action under the provisions of Drugs and Cosmetics Act & Rules and intimate to CDSCO from time to time on priority.

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy forwarded to:

1. All zonal, sub zonal and port offices of CDSCO
2. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi.
3. Under Secretary, Drugs, Ministry of Health and Family welfare, Nirman Bhawan, New Delhi.