



DRUGS CONTROL ADMINISTRATION
Government of Telangana



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O.O.No. 04/Peshi/2019.

Dated: 07.02.2019.

Sub: Amendment to the Drugs and Cosmetics Rules, 1945 regarding uploading data of Drug Manufacturing facilities and approved drug formulations on SUGAM portal - Certain Instructions Issued .

Ref: Lr No. CDSCO/IT/2018-(22), dated. 28.01.2019 of the DCG(I), New Delhi.

Vide reference cited, the Drugs Controller General of India, New Delhi has informed that, the Ministry of Health and Family Welfare has issued a gazette Notification GSR 19(E) dated 10.01.2019 amendment to the Drugs and Cosmetics Rules, 1945 regarding uploading data of Drug Manufacturing facilities and approved drug formulations on SUGAM portal and requested to take necessary action and to direct all the Manufacturers to upload the data on SUGAM portal which will strengthen the Drug Regulatory system. (Copy enclosed).

In view of the above, all the Assistant Directors and Drugs Inspectors are hereby informed to instruct all the manufacturers located in your respective jurisdictions to instruct to register and upload the details of the firms along with all drug approvals (till date) as early as possible

Hard copies of uploaded information have to be obtained and communicated to the Licensing Authority.

Preeti Meena
Dr. PREETI MEENA, I.A.S
DIRECTOR

To,
All the Assistant Directors in the State.
All the Drugs Inspectors in the State.

Copy to :
The DCG (I), New Delhi.
All the Deputy Directors in the State.
Notice Board
Website Notification Board.

CDSCO/IT/2018-(22)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, New Delhi

Dated: 28.01.2019

To

All State Drugs Controller's

Sir,

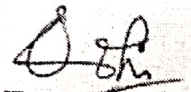
Subject: Amendment to the Drugs and Cosmetics rules, 1945 regarding uploading data of Drug manufacturing facilities and approved drug formulations on SUGAM portal – reg.

The Ministry of Health and Family Welfare has issued a gazette notification vide G.S.R 19(E) dated:10.01.2019 amending the Drugs and Cosmetics Rules, 1945 by inserting Rule 84AB - Information to be uploaded by the licensee on online portal SUGAM. As per the inserted rule, all the licensee shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information, as per the format provided in the said portal, pertaining to the licences granted for manufacture for sale or distribution of drugs and the information so provided shall be updated from time to time and such information uploaded by the licensee shall be verified by the concerned Licensing Authority. The rule is effective from the date of notification.

CDSCO has launched a module under SUGAM portal for uploading the data for this purpose. In this regard, CDSCO has also developed a user Manual (https://cdscoonline.gov.in/CDSCO/resources/app_srv/cdscoglobal/helpfiles/Manufacturer_sign_up.pdf) which will provide applicant a step by step procedure for uploading the data.

All ~~the~~ State Drugs Controllers are requested to take necessary action and direct the all manufacturers to upload the data on SUGAM portal regarding the subject cited above which will strengthen the drug regulatory system by way of improving the transparency, accountability as well as accessibility of the drugs in the country. Further, they are also requested to verify the data uploaded by the manufacturers for compliance of the provisions of the rules. In case of any technical issues you may email to it-helpdesk@cdsco.nic.in or contact IT cell at CDSCO headquarter.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy to:

1. All Pharma Associations (IDMA/IPA/FOPE/CIPI/FICCI/OPPI/Others)
2. PPS to AS & DG, MoHFW
3. PPS to JS(R), MoHFW