Nil

File No. 4-01/2018-DC (Misc. 42)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 28-03-2019

To,
All State/UT Drugs Controllers

Subject: Condition for supply of Buprenorphine 2mg/0.4mg sublingual tablet and FDC of Buprenorphine + Naloxone (2mg+0.5mg & 0.4mg+0.1mg) sublingual tablets-regarding.

Sir/Madam,

As you are aware, this office had approved Sublingual tablets of Buprenorphine 2mg/0.4mg on 10.03.1999 and FDC of Buprenorphine + Naloxone (2mg + 0.5mg & 0.4mg + 0.1mg) on 02.12.2008 with the following condition:

"The preparation shall be supplied only to the designated De-addiction centres set up by the Govt. of India funded by the Ministry of Health and Ministry of Social Justice & Empowerment and Hospitals with De-addiction facilities and a list of the centres to whom supply of the drug is made should be made to the office of Drugs Controller General (I) periodically indicating the quantity supplied to each centres".

In this regard, this office had also written to all the State Drugs Controllers vide this office letter no. 4-52/1996-DC (Pt. RUS-1) dated 24.09.2010 requesting to stipulate the above condition while granting license to manufacturers for the above drugs.

Subsequently, the Association of Psychiatrists through their representation have requested to withdraw the above restriction for supply of sublingual tablet of Buprenorphine and FDC of Buprenorphine and Naloxone sublingual tablet to De-addiction centre only by mentioning various reasons like the need of the country, extremely less availability in De-addiction centres, improper definition of De-addiction centres, which is leading to lack of access of said medicines to trained Psychiatrists.

In view of representation of Association of Psychiatrists, the proposal for deletion of the condition was placed before 38th Subject Expert Committee (Neurology and Psychiatry) in its meeting held on 08.08.2018 for deliberation wherein the Association of Psychiatrists presented their proposal before the committee.

The committee discussed the proposal and noted that the existing conditions regarding the restriction on sale and distribution mentioned in letter dated 24.09.2010 needs to be modified and recommended that Buprenorphine 2mg/0.4mg sublingual tablet and FDC of Buprenorphine + Naloxone (2mg+0.5mg & 0.4mg+0.1mg) sublingual tablets

should be allowed to be supplied to psychiatric clinics, hospitals instead of earlier condition that the drug should be supplied to de-addiction centres only.

The recommendation of the Subject Expert Committee was considered by this Directorate in consultation with the Ministry of Health and Family Welfare, Government of India and accordingly the condition laid down earlier is amended as under:-

In place of:

"The preparation shall be supplied only to the designated De-addiction centres set up by the Govt. of India funded by the Ministry of Health and Ministry of Social Justice & Empowerment and Hospitals with De-addiction facilities and a list of the centres to whom supply of the drug is made should be made to the office of Drugs Controller General (I) periodically indicating the quantity supplied to each centres".

Read as:

"The preparation shall be supplied to Psychiatric clinics and hospitals in addition to the designated De-addiction centres set up by the Govt. of India funded by the Ministry of Health and Ministry of Social Justice & Empowerment and Hospitals with De-addiction facilities and a list of the centres to whom supply of the drug is made should be made to the office of Drugs Controller General (I) periodically indicating the quantity supplied to each centres".

In view of above, you are requested to stipulate the above condition while grating licensed to the manufacturers of the said products. You are also requested to direct the existing manufacturers of the said products to comply with above conditions.

Yours faithfully,

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