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Food & Drugs Administration, Punjab,
Near Civil Hospital, Kharar, Sahibzada Ajit Singh Nagar.

Office-Order

To

- (i) All Zonal Licensing Authorities
- (ii) All Drugs Control Officers
In the State of Punjab.

No. 1555-1598
Dated: 13/8/2019

Subject: **Modification in order dated 29-7-2019 regarding; imposing specific restriction on stocking for sale and distribution of Tramadol & Tapentadol Oral Solid Dosage forms by the wholesale, retailsale licencees and RMPs in addition to already restricted 06 drugs formulations.**

This is with reference to letter No. PA/CFDA/658 dated 29-7-2019 issued by this office. The said orders have been revisited in the light of the provisions of Drugs & Cosmetics Act, 1940 and Rules made there under, and in supersession of the above referred orders, the fresh orders in this regards are hereby issued as under: -

- (i) That the Department has already restricted 6 drugs formulations containing Dextropropoxyphene, Diphenoxylate, Codeine, Pentazocine, Buprenorphine & Nitrazepam in their formulations vide letter No. 4485-4505 dated 28-3-2012, for their sale and distribution to the chemists ordinarily, however the retail sale chemists situated inside or outside the Hospitals have been allowed on request basis to stock for sale and distribution the aforementioned restricted drugs for the legitimate requirements of the patients. Similarly, the wholesale licencees who were direct / authorized stockiest of the drugs manufacturing companies engaged in manufacture of aforementioned drugs were allowed to possess above noted drugs formulations for their resale and distribution with the condition that such wholesale / retail-sale chemist will submit the monthly purchase & sale inventory before the concerned area Drugs Inspector, so that the rationality

of purchase & sale of such drugs shall be assessed and unethical trade of such drugs shall be checked.

- (ii) That with the approval of Govt. of Punjab, in the Department of Health & Family Welfare, instructions were issued vide memo No. Drugs/JC(D) Pb. 2017/63-190 dated 16-1-2017 for monitoring & regulation of sale of habit forming drugs and effective implementation of various provisions of the Drugs & Cosmetics Act 1940 and Rules 1945 under Drugs Policy 2017.
- (iii) That it is evident from various reports, news clipping appearing in the print media regarding unethical trade and misuse of Tramadol & Tapentadol containing oral solid dosage forms, tablets & capsules by the public in large for the purpose of habit forming / intoxication. The Drugs Controller General (India) has also restricted the use of aforementioned drugs vide letter No. 4943/4.12.12 dated 14-2-2014, wherein it has been directed that NDAC (Analgesic, Anesthetics & Rheumatology) in its meeting held on 22-3-2013 deliberated that Tramadol as well as Tapentadol has high potential for respiratory depression and addiction. The committee recommended that all preparations of Tramadol as well as Tapentadol should be used for severe acute pain only for a period not exceeding 5 days (copy enclosed). In the past, huge recoveries of Tramadol & Tapentadol oral solid dosage forms have been made by the officials of Commissionerate of Food & Drugs Administration Punjab and by the other law enforcing agencies., such medicines have been found to be sold without valid purchase and corresponding sales records.

On the basis of aforementioned reports, discussions & deliberations held with the stakeholders with regard to check the diversion & misuse of the aforementioned drugs, without affecting the legitimate requirements of the patients for prevention, cure & diagnosis of diseases. Government has arrived at the decision that there is urgent need to curb the menace of intoxication due to aforementioned drugs and hence there is need to restrict their availability on selected chemist shops and to prohibit the general chemists from stocking these drugs for

sale & distribution. The decision has been taken to allow the retail sale chemists situated either inside or outside the hospitals run by Government or Private managements, to make the above mentioned drugs available and accessible for their rational use, with the stipulation of quantity of drugs to be possessed at a time. Similarly, conditions of stipulation of quantity was imposed on the wholesale chemists, Distributors and C&FA dealing with these drugs manufacturing companies engaged in manufacturing of such drugs their authorized stockists / agents etc.

Therefore, in the light of discussion as above, I Pardeep Kumar, Joint Commissioner (Drugs), Food & Drugs Administration, Punjab having been appointed as Controlling & Licensing Authority under the provisions of rule 50, 59 & 68 of Drugs & Cosmetics Act 1940 and Rules 1945 notified by the Government for the above said purposes, keeping in view the situation as explained above, regarding regulating & monitoring the manufacture, sale and distribution of the drugs formulations containing Tramadol & Tapentadol oral solid dosage forms and to check their diversion / misuse, hereby restrict the availability and use of the aforementioned drugs to safe guard the public health with the following set of conditions:-

- (a) That all the Retailsale & Wholesale chemists including C&FA, Distributors, Stockiests etc. are not permitted to stock for sale & distribution the drugs formulations containing Tramadol & Tapentadol oral solid dosage forms in addition to already 06 restricted drugs in the State of Punjab through these orders and directed to return the stocks of such drugs to the manufacturers or C&FA or Distributors in writing within 15days from the date of issue of these orders and submit stock statements before the concerned Drugs Inspector. The eligible chemists shall apply before the Licensing Authority for obtaining the permission for legal possession of these drugs.
- (b) That the retail sale chemists which are situated either inside or just outside the Hospitals, or leading chemists with credible track

records situated at prominent places, who desire to stock the aforementioned drugs formulations may submit their applications online before the respective Zonal Licensing Authority of the area for seeking their possession upto 500 Tablets / Capsules of each drug inclusive of all brands at a time. Such chemists dealing with purchase & sale of aforementioned drugs will ensure to submit their monthly stock / sales statements before the concerned Drugs Inspector.

- (c) That the wholesale licencees who are direct / authorized Stockists / C&FA / Distributors of drugs manufacturing companies, who desire to stock the aforementioned drugs formulations may submit their applications online before the respective State Licensing Authority of the area for seeking the permission to possess upto 5000 Tablets / Capsules of each drug inclusive of all brands at a time. The C&FA are allowed to possess 50000 Tablets / Capsules of each drug at a time inclusive of all brands. Such chemists dealing with purchase & sale of aforementioned drugs will ensure to submit their monthly stock / sales statements before the concerned area Drugs Inspector.
- (d) That as per provisions of Para 5 of Schedule 'K' of the Drugs & Cosmetics Rules 1945, the Registered Medical Practitioners are permitted to possess the drugs formulations for dispensing to their own patients in accordance with the extent & conditions of exemption, are also restricted to possess not more than 500 tablets / Capsule at a time, each of drug Tramadol & Tapentadol oral solid dosage forms with the condition to maintain the purchase & dispensing records of such drugs in accordance to the provisions of Schedule 'K' of said Act. Such records maintained by the RMP's shall be produced before the Drugs Inspector on his / her demand at the time of inspection.

The retail sale chemists/wholesale chemists/C&FA/Distributors/RMP's, for whom the above allowed quantity is not sufficient in proportionate

to load / requirements of patients, they may apply to increase the limit being special case with proper justification in this office. These orders are being issued with the approval of competent authority.

(Pardeep Kumar)

Joint Commissioner (Drugs),
Food & Drugs Administration, Punjab

No.

Dated:

Copy is forwarded to: -

- (1) PA to Health & Family Welfare Minister for kind information of Hon'ble Health Minister please.
- (2) PA to Principal Secretary to Govt. of Punjab, Department of Health & Family Welfare for kind information of worthy PSHFW please.
- (3) PA to Commissioner, Food & Drugs Administration Punjab for kind information of worthy CFDA please.
- (4) Director Health & Family Welfare Punjab, Chandigarh for information & necessary compliance please.
- (5) Director Research & Medical Education Punjab for information & necessary compliance please.
- (6) President, Indian Medical Association, for information & necessary compliance please.
- (7) Registrar, Punjab Medical Council, Mohali for information & necessary compliance please.
- (8) All Civil Surgeons in the State of Punjab for information & necessary compliance please.
- (9) Assistant Commissioner (Drugs), for information & necessary compliance please.
- (10) President, Punjab Drugs Manufacturing Association for information & compliance please.
- (11) President, Punjab Chemist Association, for information & necessary compliance.
- (12) President, C&FA Association, for information & necessary compliance.
- (13) President, Wholesale Chemist Association, for information & necessary compliance.
- (14) President, Retailsale Chemist Association for information & necessary compliance.

(Pardeep Kumar)

Joint Commissioner (Drugs),
Food & Drugs Administration, Punjab