2 **Direction given by DCGI for drugs having adverse reaction**

2.1 DCGI has advised to all the state drugs controller throughout the country that all the manufacture of Ofloxcin (antiviral drug) formulation under your juriselection to mention stevens jonhson syndrome (SJS) / toxic epidermal Necrolysis (TEN) as an adverse drug reaction in the package insert / permotional Literature of the drug.

2.2 Tranexamic acid formulation to mention seizure/ convulsion as an adverse drug reaction in the package insert/promotional literature of the drug.

2.3 Qutiapine formulation to mention Urinary incontinence as an adverse drug reaction in the package insert/promotional of the drug

2.4 Ceflxime formulation to mention acute generalized exanthematous pusfulosis as an adverse drug reaction in the package insert/promotional literature of the drug.

2.5 Cefotaxime formulation to mention angioedema as an adverse drug reaction in the package insert/promotional literature of the drug.

2.6 Sulfasalazine formulation to mention drug rash with Eosinophilla and systemic symptoms (DRESS) syndrome as an adverse drug reaction in the package insert/ promotional literature of the drug.

2.7 DCGI has directed to all state drugs controller in the country that many manufactures use their same brand name which was originally for another drug/ FDC. Now the same brand name is used for another drug however the formulation has completely changed.

2.8In the drugs and cosmetics rules, 1945, in schedule H, in the note appended there to ,

in paragraph 4, for the word ' Steroids', the words the words "steroids or Hydroquinone shall be substituted.

3.

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

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/0.4 mg sublingual tablet and FDC of Buprenorphine +Naloxone (2mg+0.5mg & 0.4 mg+0.1 mg) 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 centers only.

The recommendation of the subject expert committee was considered by this 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 facilities and a list of the centers 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 centers"

Read as:

"The preparation shall be supplied to Psychiatric clinics and hospitals in addition to the designated De-addiction centers 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 centers 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 centers".

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