F. No. 18-06/2011-DC
Directorate of General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I))

Dated: 04 APR 2012

To,

1. All State Drugs Controllers

Sub: Limiting of Acetaminophen (Paracetamol) in Prescription Combination Products and giving Box Warning About its Liver Toxicity- recommendation of DTAB in its 59th meeting held on 24.06.2011-regarding.

Sir,

Please refer to this officer letter of even number dated 23.09.2011 on limiting of Acetaminophen (Paracetamol) in Prescription Combination Products and giving Box Warning About Its Liver Toxicity as per recommendations of DTAB in its 59th meeting held on 24.06.2011.

The office of DCG(I) has received certain representations from the manufactures asking clarification in respect of the implementation of the recommendations of DTAB. The office of DCG(I) has examined the various issues raised in these representations and the following clarifications are being forwarded for smooth implementation of the recommendations of the DTAB:

1. State Licensing Authorities may permit lowering of the contents of paracetamol to 325 mg in the already approved formulation.
2. The restriction of limiting of contents of paracetamol to 325 mg is applicable to prescription products. However, the box warning as recommended in the said letter would be required to be provided on the label of all products containing paracetamol.
3. The Fixed Dose Combinations (FDCs) containing paracetamol manufactured for export are not covered under the aforesaid letter.

4. The limiting of paracetamol in prescription combination products is required to be completed in a period of three years. The renewals of product permissions of existing formulations may continue to be granted while ensuring that the manufacturers comply with the requirements in the specified period.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

Copy forwarded for information to the Zonal /Subzonal offices of CDSCO.

राजस्थान सरकार
औषधि नियंत्रण संगठन, स्वास्थ्य भवन, तिलक मार्ग, जयपुर राज0

कमांक–डीसी/डी–2/अमेण्ड–2/2012/187 दिनांक 30.04.2012

प्रतिलिपि निम्न को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित है।

1. समस्त सहायक औषधि नियंत्रक, राज0/ समस्त औषधि-नियंत्रण अधिकारी, राज.
2. अध्यक्ष, राजस्थान फार्मास्यूटिकल्स मैन्यूफेक्चरर एसोसियशन, जयपुर।
3. इन्चार्ज, सर्वर रूम को भेजकर लेख है कि आप उक्त पत्र को विभागीय वेबसाईट पर डालने का कष्ट करें।

औषधि नियंत्रक
राज0 जयपुर