

**No.7-5/2015/Misc/ (e-Governance)/091  
Dte. General of Health Services  
Office of Drugs Controller General (India)**

FDA Bhawan, Kotla Road,  
New Delhi - 110 002  
Dated: 30.12.2015

**To**

All State/UT Drugs Controllers

**Subject: Sale of drugs over Internet contravening the provisions  
of Drugs and Cosmetics Rules, 1945**

Sir,

The Drugs and Cosmetics Rules, 1945 inter alia regulate the sale and distribution of drugs in the country. The Rules do not distinguish between the conventional and over the Internet sale/distribution of drugs. However, the provisions of the aforementioned rules have to be complied in both cases. In the recent past, a spate of representations have been received against e-Pharmacy from individuals, organizations, trade bodies etc. An analysis of the representations has revealed that serious concerns have been raised on issues impacting public health such as gross violation of the provisions under Drugs and Cosmetic Act and Rules, endangering human lives, rendering Pharmacovigilance machinery ineffective, rendering drugs recall impossible, compromise of storage conditions, danger of online sale of controlled substances, encouragement of drug addiction among youth, etc.

The Drugs Consultative Committee, a statutory body under Drugs and Cosmetics Act, 1940, in its 48<sup>th</sup> meeting, examined the issue of sale of medicines over internet and after deliberations, constituted a sub-committee under the chairmanship of Dr. Harshadeep Kamble, Commissioner, FDA, Maharashtra, to examine issue of such sales via internet, its impact on public health and also look into the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945.

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The sub-committee in its two subsequent meetings decided to invite experts from the fields of Information Technology, National Enforcement and Investigation Agencies, Medical council of India etc. to understand their views on the subject matter. The sub-committee also invited suggestions/comments from the public in this regard. The sub-committee is currently in the process of consultation with all the stakeholders.

The concerns raised in the representations, particularly those relating to violation of Drugs and Cosmetics Act and Rules made thereunder, safety and efficacy of medicines made available through online sales can not be ignored/kept pending till the report of the sub-committee constituted for this purpose becomes available.

In the above background, you are requested to put a strict vigil on online sale of medicines and take action against those indulging in online sale of medicines in violation of the Drugs and Cosmetics Act and Rules thereunder, in the interest of public health. You are also requested to disseminate this communication to all Licensing Authorities under your jurisdiction for similar action in this regard. Further, you are also requested to inform this office about the action taken from time to time in the matter.

Yours faithfully,



30/12/2015

**(Dr. S. Eswara Reddy)**

Joint Drugs Controller (I)

**Copy to:**

PPS to JS(R), Department of Health and Family Welfare, Nirman Bhawan, New Delhi