GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1575
ANSWERED ON:27.11.2009
APPROVAL OF DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether all the patented pharmaceutical drugs/products in India including those imported are registered with the Central Drugs Standard Control Organisation (CDSCO)/Drug Controller General of India (DCGI);

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether approval to such drugs/ products is given in compliance with the provisions of Drugs and Cosmetics Rules;

(d) if so, the details thereof;

(e) whether some companies have been reported to have launched a combination of drugs without getting approval of the DCGI;and

(f) if so, the details of the cases of such violation and the action taken or proposed to be taken by the Government thereon?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) & (b): The patent of drugs are granted by Indian Patent office, Department of Industrial Policy and Promotions, Ministry of Commerce & Industry. The office of Drugs Controller General (India) {DCG (I)} neither maintains list of patented drugs in India nor it is required to maintain such list under the provisions of Drugs & Cosmetics Act and Rules made there under.

(c) & (d): Approval of new drugs for manufacture and/or import and marketing are granted by the office of DCG (I) in compliance with the provisions of Drugs & Cosmetics Rules. The requirements and guidelines for approval of New Drugs are specified in Rule 122A, 122B, 122D, 122 E and Schedule Y of said Rules. From April 2007 to September 2009, total 139 New Drugs have been approved by the office of DCG (I) for manufacture and/or import & marketing in the country.

(e) & (f): As per Drugs & Cosmetics Rules, for manufacture of any new Fixed Dose Combination (FDC) of drugs, permission from office of DCG(I) is required before obtaining Licence from State Licensing Authorities (SLAs). However, some SLAs have granted licences to manufacture New Fixed Dose combinations of drugs without permission from DCG (I). Recently, it has been brought to the notice of Office of DCG (I) that FDC of Ofloxacin + Cefixime were launched by some companies without manufacturing permission from DCG (I). One SLA who initially granted approval of this FDC, has cancelled the licence. In another such case, for same FDC, the concerned SLA has been asked by the Office of DCG (I) to furnish the aspect based on which, he has granted license to manufacture this FDC and also requested to take urgent action in the matter as per Drugs & Cosmetics Rules.