अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

स.एक्स.11011/1/2011-डीएफक्यूसी/1
No.X.11011/1/2011-DFQC

भारत सरकार / Government of India
स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली
Nirman Bhavan, New Delhi
दिनांक 1 अक्टूबर, 2012
dated the 1st October, 2012

To

Principal /Health Secretaries of
All States/ Union Territories

Subject: Direction under section 33(P) of Drugs and Cosmetic Act, 1940 of cancellation of licences to manufacture drug formulations falling under the purview of 'New Drugs' including Fixed Dose Combinations (FDCs) as defined under Rule 122 (E) of the Drugs and Cosmetics Rules, 1945 – regarding.

Sir,

The Regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940. Rule 122E of the Drugs and Cosmetics Rules, 1945 made thereunder provides the definition of the term 'New Drugs'. The drugs falling under this category require prior approval from the Licensing Authority defined under Rule 21(B) i.e. the Drugs Controller General (India) [DCG (I)] before the grant of a licence for manufacture by the State Licensing Authority. As per Rule 122E, new drug shall mean and include-

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage from (including sustained release dosage from) and route of administration.

Explanation.- For the purpose of this rule-

(i) all vaccines and recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

2. Instances were brought to the notice of the Central Government from time to time that the licensing authorities of many States and Union Territories have been granting licenses for manufacture of new drugs including Fixed Dose Combinations (FDCs) falling in the category of new drug defined under Rule 122E of Drugs & Cosmetic Rules without the prior approval of the Licensing Authority defined under Rule 21 (b) in violation of the said provision of the Drugs and Cosmetics Rules. The Parliamentary Standing Committee on Health & Family Welfare has taken strong objection to this practice in its 59th Report on the Functioning of Central Drugs Standard Control Organisation (CDSCO). In the light of the observations made by the Parliamentary Standing Committee, the issue of cancellation of licences by the State Licensing Authorities for manufacture of drug formulations falling under purview of the new drugs especially in respect of Fixed Dose Combinations was accordingly discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It was reiterated in the meeting that such licence for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities.

3. In view of above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for the grant of manufacturing licenses for the drugs falling under the definition of the term 'new drug' and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the Drugs Controller General (India).

Yours faithfully

(संजय प्रसाद)
(Sanjay Prasad)
निदेशक / Director

टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.