No. 19(309)/2014/DP/Div.II/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

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NOTICE

Subject: Issues regarding fixation of retail price in respect of "new drug"

The Drugs (Prices Control) Order (DPCO) 2013, under paragraph 15(2), provides that where an existing manufacturer of a drug with dosages and strengths as specified in the National List of Essential Medicines (NLEM) launches a "new drug" as defined under para 2(u), such existing manufacturer shall apply to the Government for prior price approval of such new drug in Form-I specified under Schedule II to the DPCO 2013.

2. Paragraph 2(u) of the DPCO 2013 defines a "new drug" as a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines (NLEM) by combining the drug with another drug either listed or not listed in the NLEM or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths in the NLEM.

3. The fixation of retail price of a new drug is made under paragraph 5 of DPCO 2013 subject to fulfilment of applicable statutory requirements, including that of obtaining manufacturing licence from the competent authority under the Drugs and Cosmetics Act 1940 and Rules 1945, by the concerned manufacturers/ marketing companies.

4. For the purpose of grant of manufacturing licence, Rule 122(E) of the Drugs and Cosmetics Rules 1945 defines a new drug inter alia in part (b) and (c) as under:

"(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 form (including sustained release dosage form) and route of administration.

Explanation - For the purpose of this rule–

(i) all vaccines 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.] Under the Drugs and Cosmetic Rules, 1945 the Drugs Controller General (India) is the sole competent authority to grant manufacturing licence for a new drug,"

5. The NPPA has so far approved retail price in respect of 112 "new drug" formulations, as defined under paragraph 2(u) of the DPCO 2013 for which applications were received in the Form I of Second Schedule to the DPCO 2013 subject to meeting all statutory requirements, including those specified above. Accordingly, all applicant companies that have already received prior price approval of the NPPA for launch of a "new drug", as defined under paragraph 2(u) of the DPCO 2013, are requested to submit compliance report within one month of the date of this notification to the effect that subject "new drug(s)" in question does/ do not fall in the category of prohibited drug and has/ have the approval of the competent authority under the Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 as reiterated in DCG(I)'s letter F.No. 4-01/2013-DG(Misc-13-PSC) dated 15.01.2013 failing which NPPA would be constrained to withdraw the respective retail price notification.

5. Similarly, in respect of all pending applications received in Form-I of Second Schedule to the DPCO 2013 for which retail price is yet to be fixed, the applicant company has to submit an undertaking within 10 days of the date of this notification to the effect that the applied "new drug" possesses requisite approval of the competent authority and is not prohibited drug in terms of DCG(I)'s letter F.No. 4-01/2013-DG(Misc-13-PSC) dated 15.01.2013. Failure to comply with this requirement will lead to automatic rejection of the application in question, and the applicant will not be able to launch the product in the market. Market launch and/ or sale of a "new drug", as defined under paragraph 2(u) of the DPCO 2013 without prior approval of retail price by the NPPA or where such approval stands withdrawn shall not only attract recovery of overcharged amount along with interest and penalty but also prosecution under Section 7 of the Essential Commodities Act, 1955.

(Injeti Srinivas)
Chairman
27.11.2014