F.No. 20(37)/2005/Div-IV/NPPA
National Pharmaceutical Pricing Authority
(Legal Division)

Dated 04/10/2012

Internal Guideline No. 1 /2012

Sub: Revised Internal Guidelines for referring the case for prosecution under para 8 of DPCO,1995.

The Department of Pharmaceuticals (then Department of Chemicals and Petrochemicals) vide their D.O. no. 5/11/2005-PI.I dated 30th June 2006 directed the National Pharmaceutical Pricing Authority that in view of the decisions taken at the level of Minister (C&F&S), the NPPA, may refer the cases of violation of the DPCO, 95 against the defaulting Pharma companies to the concerned State Drug Controllers for taking penal action including prosecution.

2.0. The National Pharmaceutical Pricing Authority in its 91st Authority Meeting held on 07.02.2007 in order to have an uniform policy had approved certain guidelines for referring the cases for prosecution in respect of violations of provisions of para 8 of the DPCO,1995. Accordingly, internal guidelines no. 1/2007 were issued on 19.02.2007.

3.0. In the light of experiences gained in this regard, the aforesaid internal Guidelines were reviewed in 126th Authority Meeting held on 11.09.2012 in the NPPA. As the provisions of the DPCO, 1995 obligate manufacturers and marketing companies to take prior price approval for sale of a scheduled formulation from the NPPA / Government, any circumvention of provisions of the DPCO, 1995 from manufactures / marketing companies not only unjustly deprives poor patients from the benefits of having fair and reasonable prices for scheduled formulations as fixed by the NPPA / Government but also causes unreasonable and uneconomical burden on them.

4.0. The Authority, in order to prevent such a circumvention / violation of the provisions of the DPCO, 1995, in the aforesaid meeting felt that it is absolutely essential that manufactures / marketing companies should not sell their scheduled formulations at unauthorized and illegitimate prices to earn unjust enrichment. Therefore, in order to protect the larger public interest, the Authority decided that the manufacturers / marketing companies need to be deterred from making

any illegitimate sale of scheduled formulations at unauthorized prices without having prior price approval from the NPPA / Government.

5.0. Accordingly, the Authority has approved with necessary amendments, additions and modifications revision of above mentioned internal guidelines for referring the cases of violations of para 8 of the DPCO, 1995 to the concerned State Drug Controllers for taking penal action including launching prosecution and recovery of overcharged / unauthorizedly charged amounts together with interest thereon from defaulting companies by the NPPA / Government under the provisions of the DPCO,1995 read with Essential Commodities Act,1955. Accordingly, the following revised guidelines are issued as hereunder-

(i) Penal action for violations of para 8 of the DPCO,1995 shall be initiated against all pharma units without any distinction between the organized sector and SSI units who have not been specifically exempted by the Govt. / NPPA in terms of S.O. No. 134(E) dated 02.03.1995.

(ii) Penal action for violation of para 8 of the DPCO,1995 shall be initiated against concerned pharma companies in the uniform manner. In such cases wherein the manufacturer as well as / or marketing company has been found to have failed to take to prior price approval in sale of scheduled formulation packs then the penal action will be initiated against both companies.

(iii) Such Pharma units which are found to have prima-facie violated the provisions of para 8 of the DPCO,1995 covered under points (i) and (ii) hereinabove with a view to afford them with an opportunity to state their case before taking a final view to proceed further, will be issued with a "show cause notice" as to why action should not be initiated against that unit [for violation of para 8 of the DPCO,1995 by the NPPA].

(iv) If the reply received from the Pharma unit is satisfactory and it is found that the concerned unit has not really violated the provisions of the para 8 of the DPCO,1995, the case will be closed after getting the approval of the Member Secretary and the Chairman, NPPA.

(v) However, if the reply furnished by the Pharma unit is not satisfactory and it is felt that the concerned unit has violated para 8 of the DPCO,1995, the case will be referred to the concerned State Drug Controller for initiating appropriate action and launching of prosecution against the said unit.

(vi) If the Pharma unit does not reply to the Show-Cause Notice within the stipulated time of 21 days then two reminders would be issued to the unit for reply within a span of two months. Even after that if the Pharma unit does not furnishes any reply then the case will be referred to the concerned State Drug Controller for initiating and launching of prosecution action against the Pharma unit.

(vii) In all cases of "without price approval" suitable action will be taken to fix the price of concerned scheduled formulation packs under the provisions of the DPCO,1995.

(viii) Under the provisions of the DPCO,1995, it is mandatory for manufacturer / marketing company to sell scheduled formulations at a price fixed / notified by the NPPA / Govt. For this primary responsibility / onus lies with the manufacturer / marketing company to submit applications in forms prescribed in the second schedule of the DPCO,1995, for price fixation / revision to the NPPA / Govt. In the event, any manufacturer / marketing company sells their scheduled formulation without taking prior price approval or has failed to comply with the existing price fixed / notified for the same, if any, they will be liable to deposit the overcharged amount with interest thereon with the NPPA / Govt. under the provisions of the DPCO,1995 read with Essential Commodities Act, 1955.

Appropriate action will be also taken by the NPPA to recover the overcharged amount from the defaulting manufacturer / marketing company in such cases by treating the entire amount of sales realization as overcharged amount under para 13 of the DPCO,1995 since the said sales realization is done at unauthorized MRP printed on the label of the formulation pack from the date of marketing / sale of said formulation when initiated to date of notification for specific price fixed by the NPPA in this regard.

(ix) The manufacturer / marketing company shall be required to deposit their liability towards overcharging with interest thereon with the NPPA / Govt. In the event they failed to deposit their total dues within stipulated period then matter will be referred to the Collector for the recovery of the same as arrears of land revenue or any other methods that may be available in law.

(A.K. Gautam)
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