F.No. 20(354)/2012/Div. IV/NPPA
National Pharmaceutical Pricing Authority
(Legal – 1 Division)

Dated : 9th October, 2012

Internal Guidelines No. 2/2012

Subject: Internal guidelines for dealing with overcharging and Without Price Approval (WPA) cases

Every manufacturer or marketing company is required to follow the price fixed by the NPPA for scheduled formulation under the provisions of the DPCO'95. Wherever the manufacturer or marketing company claims that their product is not covered under the price notification / price order on the ground that the product is of different composition / pack / strength etc, the manufacturer / marketing company shall apply for price approval of the product to the NPPA. NPPA shall examine such requests on merit to decide whether a separate price is required to be fixed or the product is covered in the existing notifications and take appropriate action accordingly. No manufacturer / marketing company shall sell any scheduled formulation without approval of price by Govt. / NPPA except where the company has got specific exemption under notification S.O. 134(E) dated 02.03.1995 relating to SSI or under para 25 of the DPCO, 1995 from the Government.

2. A Committee has been constituted comprising Director (F), Director (M), Director (L-1), Dy. Director (T / BD) and Legal Consultant (Shri Chopra) to examine the issues relating to the practice followed in the NPPA based on the existing internal guidelines in regard to overcharging and without price approval (WPA) cases. The recommendations of the Committee are as under :-

(i) Any scheduled formulation manufactured and sold by a company either at a price higher than the notified price or without price approval shall be liable for appropriate action as provided for in the DPCO'95. All "price violation cases" shall necessarily fall under 'Overcharging case' or 'WPA category' or both.

(ii) (a) In cases where ceiling price notified under para 9 or specific price under para 8 of the DPCO, 1995 has been fixed by NPPA, the manufacturer / marketing company shall have to follow the notified price or price order for such formulation or the formulations which are comprehensively covered by virtue of the notes mentioned in the said notification. In respect of formulations covered under the notification as stated above and the manufacturer / marketing company is not following the said notified price on the plea that certain addition / deletion or any other change in the composition and / or packing etc have been made, the case shall be primarily treated as a case of overcharging and the action shall be initiated for recovery of the overcharged amount along-with interest.

(b) In case of overcharging, the excess price i.e. the differential amount between MRP and Notified Price, charged by the manufacturer / marketing company from the date of notification as applicable shall be recovered as overcharged amount together with interest.

(iii) In respect of all other cases where no price has been fixed or no price notification order similar / nearer to the formulation-in-question exists or where the manufacturer / marketing company still disputes overcharging on any substantial ground, the cases shall be treated as "Without Price Approval (WPA) case". The company shall be informed that in that event, the case shall be treated as WPA and NPPA shall initiate action for recovery of the entire amount of sales realization from the date of introduction of such formulation till the price is fixed / notified as "unauthorized sale", considering the fact that the concerned manufacturer / marketing company has failed to take prior price approval under DPCO, 1995. In such cases, NPPA shall also fix price of the said formulation either based on the Form-III / IV application received from the manufacturer or based on available information under para 11 of DPCO, 1995, wherever considered necessary. In addition, the matter shall be referred to the concerned State Drug Controller for initiating and launching prosecution action against the Pharma Unit by Monitoring Division

of NPPA as per the revised internal guideline considered and approved in the 126th Authority meeting held on 11.09.2012.

(iv) Even after notifying a separate price, if any manufacturer / marketing company violates the price notification in the subsequent period, then the excess price charged by the manufacturer / marketing company from the date of notification shall be recovered as overcharged amount with interest thereon.

(v) For sale pertaining to the period prior to the fixing of a separate price or a ceiling price for the product, appropriate actions shall be initiated for recovery of the entire sale amount treating entire sale proceeds as 'Unauthorised Sales' against nil price for the period starting from the date of introduction of the product in the market till issue of the price notification order. Such action would be in line with the revised guidelines approved in the 126th Authority meeting held on 11.09.2012.

(vi) Where specific exemption has been granted to a SSI unit under SO 134(E) dated 02.03.1995 the benefit of such exemption shall be available only to those products which were in existence at the time of granting exemption by the Government or NPPA under the said notification.

(vii) This shall be applicable to all overcharging / WPA cases irrespective of any annual turnover limit.

(viii) In respect of WPA cases detected by NPPA after the issue of internal guideline no. 1/2007 where price for the formulation has been fixed by NPPA, but company has not been booked for overcharging for selling the product without price approval, if any, pertaining to the period prior to fixation of price of the said formulation, the entire sale amount from the date of introduction of the product in the market till issue of the price notification order shall be recovered from the company treating the entire sale proceeds as 'Unauthorised Sales'. In addition, the matter shall be referred to the concerned State Drug Controller for initiating and launching of prosecution action against the Pharma Unit by Monitoring Division as per the internal

guideline No. 1/2007 dated 19.02.2007 and Office Order No. 21(6)/2009/Enf./NPPA dated 02.09.2009. This shall also apply to cases noticed after issue of revised internal guideline as approved in 126th Authority meeting held on 11.09.2012. A copy of the guideline approved in 126th meeting is annexed.

(ix) In respect of cases lying sub-judice in various courts, appropriate action will be considered by NPPA depending upon the directions / order / judgement passed by the Hon'ble courts in such cases.

(x) The above guideline shall be put in place prospectively. All the present cases under different stages of examination, excepting for cases where 'show cause' / demand notice has already been issued, shall be processed as per this revised guideline.

(A. K. Gautam)
Member Secretary

Copy to:-

(i) Director (Legal-1), NPPA
(ii) Director (Monitoring), NPPA
(iii) Director (Formulation), NPPA
(iv) Director (Administration), NPPA
(v) Legal Consultant (Shri Chopra), NPPA
(vi) Sr. PPS to Chairman, NPPA for information please.