

File No.28(10)/2016/Div.IV(OC-II)/NPPA  
National Pharmaceutical Pricing Authority  
Department of Pharmaceuticals  
Ministry of Chemicals & Fertilizers  
Government of India

YMCA Cultural Centre Building,  
5<sup>th</sup> / 3<sup>rd</sup> Floor, 1, Jai Singh Road,  
New Delhi-110001  
Date: **31.03.2016**

To

Joint Secretary,  
(Shri Sudhansh Pant)  
Department of Pharmaceuticals,  
Shastri Bhawan, New Delhi.


Sub: Internal Guidelines regarding identification & initiating action for recovery  
in cases of Overcharging by companies under DPCO, 2013.

Sir,

I am to refer to the Internal Guidelines dated 22.03.2016 as approved by the Chairman, NPPA, sent to your office vide letter dated 22.03.2016 and to say that the same were placed before the Authority at its 27<sup>th</sup> meeting held on 29.02.2016. The Authority after critically examining the same suggested some modifications to the guidelines. All the modifications as suggested by the Authority have been carried out and a copy of the same is enclosed herewith for kind information.

Yours faithfully,

Encl.: As above.

  
(Dr. Sharmila Mary Joseph)  
Member Secretary

**National Pharmaceutical Pricing Authority  
(Overcharging Division)**

**Guidelines for Overcharging Cases**

F.No.28(10)/2016/Div.IV/NPPA

National Pharmaceutical Pricing Authority  
(Overcharging Division)

Dated: 30<sup>th</sup> March, 2016

**Internal Guidelines**

**Sub: Guidelines regarding identification & initiating action for recovery in cases of Overcharging by companies under DPCO, 2013.**

DPCO, 2013 provides that the Government shall by a notice require the manufacturers to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under various provisions of DPCO, 2013 along with interest @ 15% thereon from the date of deposit of overcharged amount. Contravention of provisions of the DPCO is also punishable in accordance with the provisions of Essential Commodities Act, 1955. Accordingly, in case any manufacturer is found to be not complying with the provisions of DPCO, action is initiated by the NPPA for recovery of the overcharged amount along with interest and with or without penalty as arrears of Land Revenue in accordance with Section 7A of Essential Commodities Act, 1955.

2. In order to rationalise and expedite the monitoring, enforcement and recovery process in overcharging cases, and make it time bound and more transparent in implementation, following guidelines shall be followed by the NPPA in supersession of all previous internal guidelines in this regard.

**3. Monitoring and Examination in M&E division:**

- (a) The M &E division shall constantly monitor and identify cases of over pricing from different sources. It will follow a well defined procedure in identification, examination and short-listing of prima facie actionable cases of overpricing and submit such cases to Overcharging division for further action along with a note explaining the reasons thereof. M&E

division shall categorise all cases under scheduled / non-scheduled drugs and also specify the provision of DPCO, 2013 which has been violated.

(b) M&E division shall also keep all the information sent by companies in various Forms in well organised folders so that it can be retrieved without delay for price comparison as and when required. Data on IPDMS shall also be utilised for such purpose.

**A. Overcharging cases based on sample purchases by NPPA, SDCs and other source.**

The M&E Division shall first examine all such cases based on the consolidated price list in Form II and Form V furnished by the companies or available on IPDMS as per Para 24 and 5 of DPCO, 2013 and examine if an overcharging case is made out. In order to do this, proper filing and indexing of all Form II & Form V shall be done by the M&E division.

- (a) If the company has not already furnished the information in Form II and Form V or the information is not enough to draw a conclusion, the Monitoring division will send one time-bound prescribed preliminary notice (PN) to the company and seek requisite information on the prescribed format within 21 days from the date of receipt of the PN or 30 days from the date of issue of PN.
- (b) If the reply is not received within the prescribed time limit or if it is received but not found satisfactory after examination, the case shall be referred to Overcharging division with its comments, within seven working days from the date of receipt of the reply.
- (c) If on comparison with Form II and Form V or based on the information received from the company in reply to PN no overcharging is found, the case shall be dropped by NPPA with the approval of MS. The company shall be informed of it accordingly only if a PN has been issued to the company.
- (d) The Monitoring division shall not give any opportunity of personal hearing to the company even if there is a request and shall not continue to hold any case beyond a period of 60 days as undecided,

about its actionability. Director, M&E shall constantly monitor all such cases in this regard.

- (e) The PN shall be sent by post to the registered address of the company and addressed to its MD or CEO. Copy of the PN shall also be sent through email and fax if available.

**B. Cases, identified on the basis of Pharmatrac data:**

- (a) The M&E division will first ensure 100% cross checking of Pharmatrac data depending upon the category of the overpricing with the Form II and Form V submitted by the companies and kept by the M&E division. If no overpricing is found, such cases shall be dropped with the approval of MS.
- (b) If the Form II or the Form V data about the company is not available, the M&E division shall follow the same procedure as prescribed in 4(a) to 4(e).

**4. Procedure to be followed by Overcharging Division:**

The Overcharging division shall observe following procedure for dealing with all overcharging cases both under Para A and B.

- (a) Overcharging division shall further examine all cases referred by M&E division based on the available information and Pharmatrac data to find out the existence and extent of overcharging. If there is no overcharging, based on the information provided by the company in reply to PN and / or other available material the case will be proposed for closure, specifying the reasons for the same and approval of Chairman shall be taken in all such cases.
- (b) In cases where the company has provided complete and satisfactory information in reply to preliminary notice by the Monitoring division and accepted overpricing in full or partially the overcharging division shall, after careful examination, issue demand notice (without issuing SCN) to the companies with quantification of overcharged amount and interest with or without penalty, as the case may be based on CA / CMA certified data. All such cases shall be examined within a period of 10 working days from the date of receipt of the

reply of the company and the demand notices should be issued accordingly.

- (c) In cases, where the companies have not provided data in reply to PN, the Overcharging division shall issue one show-cause notice (SCN) to the companies based on the Pharmatrac data and give an opportunity to furnish required information on the same format as in the preliminary notice. If reply is not received within 30 days of the date of issue of the letter, NPPA will issue demand notice as prescribed under the relevant provision of DPCO, 2013 based on Pharmatrac and other available data quantifying overcharged amount and interest with or without penalty, as the case may be and also upload the demand notice on NPPA's website.
- (d) In cases, where SCN with quantification of overcharged amount and the interest thereon has been issued based on Pharmatrac data and written submission made by the company in response to SCN is either acceptable / partially acceptable or non acceptable a speaking order shall be passed while giving point wise reply to their contention and either a demand notice shall be issued as per the prescribed para of DPCO, 2013 or the case shall be dropped with the approval of the Chairman.
- (e) In cases where neither reply from the company nor the Pharmatrac data is available, one show-cause notice (SCN) will be issued with in-principle general quantification of overcharged amount. The companies may be given one last opportunity to furnish the production and sales details on the same format as prescribed in the preliminary notice. The companies will be required to show cause within 21 days from the date of receipt of the notice.
- (f) In cases under above sub para 5(e), if NPPA has failed to get any reply, from the companies within 30 days of issue of the notice the matter will be referred to SDC's through the Principal Secretary / Secretary (Health) in the State where the company's headquarter is situated with a request for pressing upon the companies to furnish required information within a further period of 30 days and also to

verify the credentials of the company through inspection of its offices and factory premises if need be. A reminder may follow giving another 21 days time if information is not received.

- (g) If NPPA does not receive any information from SDC even after expiry of the time limit set in the reminder, it will issue a pre-prosecution notice by uploading it on NPPA website, giving another 15 days time from the date of notification for a response from the company. If no reply is received, NPPA will prosecute the company as prescribed under Section 7 of the Essential Commodities Act.
- (h) If any company makes any representation, after the issue of the demand notice, same may be examined only if there is any new and acceptable contention and the demand may be modified or dropped after very careful examination and with the approval of the Chairman.
- (i) If the companies do not deposit the demanded amount within the prescribed time limit of 30 days, only one time-bound reminder giving another 21 days time to deposit the money will be issued. Even after issuance of one reminder if the companies do not deposit the same, the matter will be referred to Collector to initiate recovery proceedings against the companies and such information shall be uploaded on NPPA website.
- (j) In all cases recovery of overcharged amount and interest, with or without penalty, as the case may be shall be completed within a period of 3 months from the date of issue of the demand notice. Any further extension shall be done with the approval of Chairman if there is any justification.
- (k) Where the cases of recovery of overcharging amount are pending before the Court, the case shall be processed / followed up as per the directions of the Court. In respect of other cases pending before quasi-judicial Authorities like BIFR, etc. reference shall be made to the concerned authority to safeguard the interest of Government.

- (I) All the SCN, DN and other communications to companies shall be done not only through Speed post / UPC but also through email and fax wherever such details are available.

**5. Overcharging cases under Para 15 of DPCO, 2013**

- (a) In any case where a company is found to be selling any drug without price fixation under para 5 read with para 15 of the DPCO, 2013 the manufacturer shall be liable to pay the overcharged amount along with interest as per Para 15(5) of the DPCO, 2013 in addition to penalty. On identification of such cases from any source, a show-cause notice giving 21 days time shall be issued as in other cases.
- (b) On the issue of SCN if the company replies to SCN, same shall be thoroughly examined within 10 working days and if no violation is found, case may be dropped with the approval at the competent level. However, in case of unsatisfactory reply, NPPA will fix such price as prescribed under DPCO, 2013 and issue demand notice.
- (c) If the company has not responded to show-cause notice, NPPA after issuing one reminder giving another 15 days time shall fix the price of such medicine and calculate the overcharging amount based on the difference between the prices. A penalty amount not less than 100% of the principal amount shall necessarily be imposed in such cases and demand notice be issued, giving 30 days time to deposit the money.
- (d) However, if the company had applied to NPPA as prescribed and the price fixation was pending at NPPA, a lower penalty or its waiver may be considered on case to case basis.
- (e) If the company fails to deposit the money within the stipulated time and does not respond to NPPA, a recovery certificate to concerned Collector will be issued and NPPA will start prosecution of the company under section 7 of the E.C. Act after issuing a pre-prosecution notice giving 15 days time to the company to respond.

**6. General guidelines to be taken into account in dealing with overpricing cases.**


Apart from the above, the following principles shall be followed in all cases.

- (a) These guidelines shall be uniformly applied in all cases. Any exception in this regard shall need to be brought to Chairman's knowledge and his approval to be taken after explaining the circumstances and justifications of the same.
- (b) The provision of penalty under Para 15 and Para 20 of DPCO, 2013 apart from the overcharged amount and the interest on that shall be imposed in all such cases wherever applicable.
- (c) In all the test sample purchase cases, NPPA shall also take action against concerned retailer under para 26 or 27 as the case may be for overpricing.
- (d) All cases of overcharging where the companies have not deposited the money or have delayed the same after expiry of the given time, shall be referred to Collector for recovery of the amount as arrears of Land Revenue irrespective of any monetary limit.
- (e) Only one personal hearing may be accorded to any company on the written request by the company at any stage. Personal hearing shall be done at the level of Member Secretary, NPPA in the presence of other concerned officers.
- (f) Details of cases where the defaulting companies are not responding to the NPPA's communication even after prescribed time limit, shall be uploaded on the NPPA's website as public notice under the categories of 'show cause notices' and 'demand notices' as the case may be. However, the M&E and the Overcharging division will always verify the address of the company before issuing PN / SCN / DN etc.
- (g) All notices sent by post shall also be faxed and e-mailed on the registered phone number and e-mail id.



These guidelines shall be applicable with immediate effect and shall apply to all pending cases as well. It will also be uploaded on the NPPA's website in order to bring in more transparency in the functioning of NPPA.

Sd/-  
**Chairman, NPPA**

Issued  
  
Director (OC), NPPA