National Pharmaceuticals Pricing Authority
(Overcharging Division)

Guidelines for Overcharging Cases
F.No.28(10)/2016/Div.IV/NPPA
National Pharmaceutical Pricing Authority
(Overcharging Division)

Dated: 7th October, 2016

Internal Guidelines

Sub: **Guidelines regarding identification and initiating action for recovery in cases of Overcharging by manufacturers and/or marketers under DPCO, 2013, DPCO, 1995 and DPCO, 1987 – reg.**

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The DPCOs empowers the Government to recover from the manufacturers, the amount accrued due to charging of prices higher than those fixed or notified by the Government under various provisions of the DPCOs along with interest @ 15% thereon from the date of overcharging. Contravention of provisions of the DPCOs 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 DPCOs, 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.

Under paragraphs 14(2), 15(5) & (6), 16(5) of DPCO, 2013, in case of violation, concerned manufacturer is liable to deposit the overcharged amount with interest thereon from date of such overcharging in respect of scheduled formulation. Under paragraph 20 of the DPCO, 2013 in respect of non-scheduled formulation, the manufacturer is liable to deposit the overcharged amount along with interest thereon from date of increase in price in addition to the penalty. Paragraph 23 of DPCO, 2013 empowers recovery of overcharged amount under DPCO, 1987 and 1995. Paragraph 22 of DPCO, 2013 deals with recovery of dues under the DPCO, 1979.

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 suppression of all previous internal guidelines in this regard.

2. Monitoring and Examination in M&E division:

(a) The M&E division shall constantly monitor and identify cases of overpricing from different sources. It will follow a well defined procedure in identification, examination and shortlisting 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 manufacturers in various Forms in well organised folders so that it can be retrieved without delay for price comparison as and when required. Subsequently, the data on IPDMS shall also be utilised for such purpose.

3. 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 F orm I, Form II and F orm V furnished by the manufacturers or available on IPDMS as per Para 15, 16, 24 and 25 of the DPCO, 2013 and verify the fact of overcharging. The manufacturer and dealers both will be responsible for overcharging on jointly or severally basis.

(a) If the manufacturer has not already furnished the information in Form I, Form II and Form V or the information is not enough to draw a conclusion, the Monitoring division will send the prescribed time-bound 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. The company shall provide requisite details duly certified by CA/CMA along with verification given at Annexure-I to these guidelines.

(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 I, Form II and Form V or based on the information received from the manufacturer in reply to PN no overcharging is found, the case shall be dropped by NPPA with the approval of MS. The manufacturer shall be informed of it accordingly only if a PN has been issued. In case of pre-manufactured stock, the procedure as given in para 7 shall be followed.

(d) The Monitoring division shall not give any opportunity of personal hearing to the company even if there is a specific request for the same.

(e) In sample purchase cases of overpricing, PN/SCN shall be issued to both manufacturer as well as concerned drug retailer.

(f) Wherever there is strong evidence to establish that the dealer or retailer selling overpriced medicines has done so with the knowledge of the price reduction, NPPA will also take action against such dealer along with the manufacturers.

(g) M&E division shall not continue to hold any case beyond a period of 60 days as undecided, about its action ability and inform cases belong 60 days in the monthly information system reporting.

(h) In case of overcharging complaint relates to any billing done by hospitals/ nursing homes etc. in violation of Para 26, similar overpricing proceedings will follow against such entities.

4. 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 I, Form II and Form V submitted by the companies on IPDMS platform. If no overpricing is found, such cases shall be dropped with the approval of the competent authority.

(b) If the Form I, Form II or the Form V data about the manufacturer is not available, the M&E division shall follow the same procedure as prescribed in 3(a) to 3(e).

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

The Overcharging division shall adopt following procedure for dealing all overcharging cases both under Para 3 and 4.

(a) For price violation cases related to PharmaTrac data, preliminary notices may be issued after checking the data on IPDMS as far as possible. If there is no overcharging, based on the information provided by the manufacturer in reply to PN and/or other available material the case will be proposed for closure, specifying the reasons for the same.

(b) In cases where the manufacturer 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) with quantification of overcharged amount and interest with or without penalty, as the case may be, based on CA/CMA certified data with required verification by the manufacturer. All such cases shall be examined within a period of 15 working days from the date of receipt of the reply of the company and the demand notices should be issued accordingly and also uploaded on NPPA website.

(c) In cases, where the manufacturer have not provided data in reply to PN, the Overcharging division shall issue one show-cause notice (SCN) 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 d ata, q uantifying overcharged amo unt and interest with or without penalty, as the case may be and update the information on NPPA 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 manufacturer 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.

(e) In cases where neither reply from the manufacturer nor the PharmaTrac data is available, one show-cause notice (SCN) will be issued on the basis of available information. The manufacturer may be given one last opportunity to furnish the production, sales and recall data, if any, on the same format as prescribed in the preliminary notice. The manufacturers 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 NPP A fails to get any reply from the manufacturer within 30 days of issue of the notice, the matter will be referred to SDCs with a copy to the Principal Secretary/Secretary (Health) in the State where the manufacturers' headquarter is situated with a request for pr essing upon them to furnish required information within a further period of 30 days and also to verify their credentials through inspection of their 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 Essentials Commodities Act, 1955.

(h) If any manufacturer makes any representation, after the issue of the demand notice, same may be examined only if there is any new and acceptable contention supported by solid evidence and the demand may be modified after very careful examination.

(i) If the manufacturers 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 manufacturer do not deposit the same, the matter will be referred to concerned District Collector to initiate recovery proceedings against them and such information shall be uploaded on NPPA website.

(j) In all cases the proceedings for recovery of overcharged amount and interest, with or without penalty, as the case may, be shall be completed within a period of three months from the date of issue of the demand notice as far as possible.

(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 the Government.

6. 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 manufacturer 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 based on the price difference.

(c) If the manufacturer 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, in cases where the manufacturer had applied to NPPA for price fixation as prescribed and the price fixation was pending with NPPA, a lower penalty or its waiver may be considered on case to case basis.

(e) If the manufacturer 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 manufacturer under Section 7 of the E.C. Act after issuing a pre-prosecution notice giving 15 days' time to the manufacturer to respond.

7. Pre-manufactured stock and calculation of overpricing

(a) The pre-manufactured stock is the quantity of a scheduled formulation produced or available in the market before the date of price notification of ceiling price and which is available for sale after the date of revised price notification.

(b) In order to ascertain the actual quantities of the pre-manufactured stock, NPPA shall ask the companies to furnish data regarding the batch wise production, batch wise sale to C&F Agent/Distributor, the recalled quantity if any, the 'physician samples' not meant for sale and the stocks destroyed on expiry etc. wherever applicable. This information needs to be verified by a Chartered Accountant/ Cost Accountant and submitted in original along with the mandatory declaration by the company as prescribed in Annexure-I.

(c) 'cut-off date' for seeking data/information as in para 7(b) shall be the period from the date of sample seizure of overpriced batch or date of the relevant notification of price (whichever is earlier), to the date of manufacture of any subsequent batch at the price notified by NPPA or the expiry period of the seized overpriced sample (whichever is later).

(d) If the overpricing case is made out based on the evidence of a pre-manufactured stock at a higher price than notified ceiling price, either based on a sample or market data, the entire quantity of such stock as defined in para 7(a) shall be taken as the quantity for calculation of overcharged amount after deducting the permissible quantities as described in Para 7(e) and (f).

(e) Permissible exclusions from overcharging stock if duly supported by undisputable documentary evidence(s), shall be: (i) the quantity of medicines recalled by the manufacturer after price revision; (ii) quantities recalled because of expiry or for any other reason; (iii) quantities on which revised MRP was

printed or pasted; (iv) quantity of physician samples not for sale. (v) quantities already sold before the date of notification and no more available in the market or trade channel.

(f) In order to claim exclusions of overpricing quantities from the calculation, the burden of proof under para 7(d) and 7(e) will be with the manufacturers who may submit additional documents even if not asked by NPPA in support of their contention.

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

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

(a) For overpricing purpose the term manufacturers shall include 'marketer' and the complete distribution chain including dealers/retailers.

(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 without exception.

(c) In all the test sample purchased cases, NPPA shall also take action against concerned retailer under Para 26 or 27 of the DPCO, 2013 as the case may be for overpricing.

(d) All cases of overcharging where the manufacturers 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. The companies shall, however, have option to seek personal hearing at the level of Chairman but they can exercise only one of these options.

(f) Details of cases where the defaulting manufacturers are not responding to the NPPA communication after being given prescribed time limit, shall be uploaded

on the NPPA's website as public notice u nder the categories of 'show cause notices' and 'demand notices' as the case may be.

(g) The M&E and the Overcharging division will always verify the address of the company before issuing PN/SCN/DN etc. All notices sent by post shall also be faxed and e-mailed on the registered fax number and e-mail id and it should be addressed to the MD/CEO or Proprietor of the Pharmaceutical company as the case may be.

(h) If notices or letters issued are returned undelivered and on examination it is found that the company is not accepting the communication deliberately, the concerned SDC will be requested to ensure delivery as under Para 8(g). Failing to get any result, an F.I.R should be lodged in such cases as under Essential Commodities Act, 1955.

(i) Whenever on examination of NPPA notices (PN, SCNs or DNs) the manufacturers have given satisfactory reply or deposited the overpricing amount with NPPA as prescribed, the case may be closed with the approval of the competent authority.

These guidelines shall be applicable with immediate effect. It will also be uploaded on the NPPA's website in order to bring in transparency in the functioning of NPPA.

Sd/-

Chairman, NPPA

Issued by

(A.P S.Sawhney)

Director (OC)

ANNEXURE-I

Verification

I, _____ son/daughter of _____ aged _____ working as _____ in the office of _____ (Name of Company) _____ at _____ (Address) _____ declare to the best of my knowledge and belief that information/details provided hereinabove or annexed herewith in respect of production and sales of the _____ (Name) formulation during the period from _____ to _____ are correct, complete, truly stated and duly certified by _____ (Name of Chartered Accountant/Cost Accountant with membership number) on the basis of factual and complete records. I, do hereby verify the correctness of factual contents in the above information/details which are derived from the records maintained in the company and nothing material facts have been concealed or suppressed. I further declare that, I am competent to furnish the above information/details and verify it.

Verified at _____ on this _____ day of _____, 2016.

(Authorised Signatory)

Name:

Designation:

Place: