F. No.19 (78)/2016/Div.II/NPPA
Government of India
Ministry of Chemical and Fertilizers
National Pharmaceutical Pricing Authority
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3rd & 5th Floor
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001.

Dated: 13.4.2017

OFFICE MEMORANDUM

Subject: Guideline and Standard Operating Procedure for disposal of review cases by NPPA

Reference: NPPA O.M. Nos. 8(40)/2017/Div.II/NPPA dated 28.3.2017 and O.M. 8(34)/2016/Div.II/NPPA dated 07.02.2017.

On the issue of compliance of review orders of the Government with regard to notified ceiling prices of scheduled formulations or retail prices of new drugs, it has been found that cases get inordinately delayed because of non-submission of necessary documents by the pharmaceutical company(ies) which initiated such review petitions. NPPA notifies the prices of essential medicines after uploading 'draft provisional price working sheet' on its website to provide an opportunity to companies to make representations, if any. Such representations are taken into consideration by NPPA before notifying the final ceiling prices. Most of the review orders issued by the Department of Pharmaceuticals are related to 'reconsideration of documents submitted by the companies'. It is found that for several months companies do not submit the required documents despite several reminders to this effect. This situation is unwarranted. Therefore, in supersession of all earlier O.Ms. in this regard, following standard procedure shall be adopted by NPPA for examination of review cases.

1. Once the review order is passed by the Department, it will be the responsibility of the petitioner company(ies) in review case to submit all necessary documents in support of their contentions within a period of 15 days from the date of the review order. If the documents are not submitted by the petitioner(s), Pricing Division shall submit the file to Member Secretary/Chairman for orders. No letter shall be issued by NPPA in this regard.

2. The companies claiming that PTR or any market data taken in NPPA's calculations is incorrect, shall submit following documents in support of their contention: -

   i) Copy of the invoice of the relevant month (August 2015 in case of scheduled formulations listed in NLEM, 2015) duly certified by the competent authority of the company with name, designation, seal, signature, mobile no. and other details.

   ii) The original sample of the drug clearly showing Batch no., MRP, Mfd. date and other details.

   iii) If the sample is very costly, the certified copy of the drug should be submitted and the sample may be presented for inspection to Advisor, NPPA/Director (Pricing) any time during office hours. Concerned officers will endorse the inspection summary on the Xerox copy of the sample and the same will be returned to the company's representative.

3. If the review petitioner has referred the PTRs or other information relating to some products of the other company(ies), the onus of submitting all the required documents along with samples as per para (2) lies with the review petitioner(s). This information, too, needs to be submitted within 15 days from the date of the review order.

4. On receipt of the documents from the companies, the NPPA office will seek the comments of Pharmatrac within maximum of five working days and Pharmatrac will be under obligation to submit its comments within 72 hours of receipt of e-mail query from NPPA.

5. Once the exercise as per paras 2-4 is completed, the Pricing Division must examine the file and put up for orders of the competent authority within five working days and the matter shall be listed as agenda for the subsequent Authority meeting for formal approval/decision. If the matter is of routine nature, NPPA will notify the revised prices with the approval of the Chairman and take post facto approval of the Authority.

6. Once Authority has approved the revised prices in compliance of the review order, NPPA office shall issue the revised notifications within three working days from the date of such approval by the Authority.

7. All efforts shall be made by the Pricing Division to dispose off the review cases within the stipulated time in the review order, as far as possible. All cases beyond 30 days shall be put up for the perusal/orders of the competent authority within a week explaining the reasons for delay.

Strict compliance of these orders shall be ensured by Director (Pricing). Status report will be put up for the perusal of NPPA Authority as a regular agenda item in every meeting.

(Bhupendra Singh)
Chairman, NPPA
13/4/17

Copy to-

All Apex Pharma Associations i.e. OPPI, IDMA, AISSPMA, FICCI, CII, IPA and FOPE for information & necessary action please.