F.No.8(18)/2014/DP/NPPA/Div.II NATIONAL PHARMACEUTICAL PRICING AUTHORITY

Internal guidelines for making representation to NPPA against price notifications

NPPA in its 18th Authority Meeting held on 15.09.2014 have approved the following guidelines in supersession of Circular dated 24.09.2013 and 09.10.2013 issued vide F.No.3/Misc./Adv/2013-NPPA for making representation to NPPA for price correction against price notifications issued under the DPCO 2013 in order to bring in consistency, objectivity and transparency:-

- a. Applicant has to first comply with the price notification. In case of noncompliance, representation would not be entertained at all.
- b. Any manufacturer making a claim about a particular PTR/MRP should have necessarily reported the same price in the return submitted by them in Form V of Schedule II to the DPCO 2013, to the NPPA, and the onus of providing documentary evidence in this regard shall lie with the applicant(s).
- c. Only market based data would be entertained, i.e., the data should be verifiable with the data base of IMS Health and/or Pharma Trac and Form V submitted by the manufacturers concerned, and no other data shall be considered.
- d. No application will be entertained beyond a period of fifteen days of the date of publication of the notification in the Official Gazette;
- e. The case of Applicant whose review petition on the same matter is pending with the Government would be considered after final orders/directions of the Government.

The proposed guidelines are applicable with prospective effect covering all pending cases at various levels as on date.