

F. No. 31015/27/2016-PI.I
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
(Pricing Division)

**‘B’ Wing, 3rd Floor, Janpath Bhawan,
New Delhi, dated the 22.09.2016**

To

**The Chairman
National Pharmaceutical Pricing Authority (NPPA)
3rd/5th Floor, YMCA , Cultural Centre Building
1, Jai Singh, Road, New Delhi-110001.**

Sub:- Observation of Standard Operating Procedure (SOP) in the light of Para 11 (3) and 11(4) of Drugs (Prices Control) Order ((DPCO), 2013 by NPPA – reg.

Sir,

I am directed to refer to the subject mentioned above and to say that in the recent past, many review petitions/representations have been received in the Department seeking separate pricing of their products in the light of Para 11 (3) and (4) of DPCO, 2013. The matter has been examined and it has been decided to direct NPPA to develop a Standard Operating Procedure (SOP) for dealing with all cases which would be covered under the ambit of Para 11 (3) of DPCO, 2013. A case in point is the review petition of M/s Cipla Limited against price fixation of Budesonide Inhalation 100 mcg and 200 mcg etc. vide NPPA order No. S.O. 1561 (E) dated 29.03.2016 to consider the matter under Para 11 (3) and 11 (4) of DPCO, 2013. A copy of review order of even number dated 14.09.2016 in respect of M/s Cipla Limited is enclosed.

2. Any case wherein a claim for separate pricing in the light of Para 11 (3) and 11 (4) of DPCO, 2013 is made, it needs to be examined by NPPA in the light of recommendations of the Expert Committee. All such cases should first be referred to the Expert Committee constituted under 11 (4) of DPCO, 2013 for its recommendations. Based on the recommendations of the said Committee, the NPPA should give its decisions and while placing its decisions on the website, the recommendations of the Expert Committee on the issue should also be placed on the website.

Yours faithfully,

(M. K. Bhardwaj)
Deputy Secretary to the Govt. of India
Tel.: 23752664
Fax: 23359301

Copy to:- Technical Director, NIC, A-Wing, Shastri Bhawan, New Delhi for uploading on Department’s website.

