



What's New

22.09.2016

DoP directs NPPA to develop SOP for dealing with cases covered under Para 11 (3) and 11(4) of DPCO, 2013

Department of Pharmaceuticals (DoP) is receiving many review petitions/representations from pharma manufacturers across the country, seeking separate pricing of their products in the light of Para 11 (3) and (4) of DPCO, 2013, the DoP has directed the National Pharmaceutical Pricing Authority (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 filed by 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.

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.

As per review order of even number dated 14.09.2016, M/s Cipla Limited contended that the NPPA has issued an erroneous notification because the NPPA has failed to recognize that their products have a different packaging and helps dosage compliance and hence it should have a different price fixed for itself; and in case of the product "Formoterol 6 mcg + Budesonide 200 mcg inhaler per dose – (autohaler) – Breath Actuated Device, the calculation by NPPA is erroneous because the data provided in the working sheet is wrong. The company submitted that their products fall under the provisions of 11(3) and hence the same should be treated differently by way of fixing pricing specifically for this.

In view of the discussion held, the reviewing authority DoP ordered, "NPPA shall examine this case in accordance with para 11(3) & (4) of DPCO, 2013. The petitioner may bring any relevant data, copies of invoices to retailers/MAT data/Samples of Budecort 100/200 inhaler with dose counter, Foracort 100/200/400 inhaler with Dose Counter and Foracort 200 Autohaler, before the Expert Committee. The recommendations of Expert Committee may be examined by NPPA on merit and the ceiling price of aforesaid formulation be fixed afresh in the light thereof. The review petition of the company is hereby disposed off accordingly".

[Observation of \(SOP\) in the light of Para 11 \(3\) and 11\(4\) of Drugs \(Prices Control\) Order \(\(DPCO\), 2013 by NPPA – reg.](#)