

F. No. 19(78)/2014/Div.II/NPPA
Government of India
Ministry of Pharmaceuticals
National Pharmaceuticals Pricing Authority

YMCA Cultural Center Building
1, Jai Singh Road
New Delhi – 110001
Date: 10.02.2015

OFFICE MEMORANDUM

Subject: Retail Price fixation of New Drug under DPCO, 2013.

In the 20th Authority meeting held on 05.02.2015, the Authority discussed the issues relating to fixation of retail price based on Form-I applications received from the manufacturers / marketing companies for a 'new drug' under DPCO, 2013. After deliberations, it was decided that in continuation of decision taken by the Authority in 19th meeting stating that the manufacturing permission granted by the State Licensing Authority before 01.10.2012 and/or its renewals thereafter, if applicable, (as per DCG(I) order F. No. 4-01/2013/DC (Misc 13-PSC) dated 15.01.2013) will continue to be in operation, pending outcome of DCG(I)'s review. Similarly, Form-I applications of 'new drug' based on such manufacturing permission will be considered for price fixation under DPCO, 2013 as well as cases having DCGI approval before or after 01.10.2012 will also be considered. It was further decided that:-

(i) Applications where the manufacturer and marketer are two distinct legal entities, the same shall be considered for price fixation under DPCO, 2013 subject to the condition that the application in Form-I is duly supported by necessary documents, including License with explicit mention of the manufacturing company and marketing company as well as an agreement/contract entered into between the manufacturer and marketer for this purpose.

(ii) As clarified by the representative of DCG(I), as per amended Rule 122E clause (c) vide GSR 724(E) dated 07.11.2013 issued by Deptt. of Health, Ministry of Health & Family Welfare, any formulations as included in India Pharmacopoeia (IP) till 07.11.2013 has deemed approval of DCG(I) for manufacturing / marketing in the country. Accordingly, cases having formulations included in IP till 07.11.2013 will also be considered for price fixation under DPCO, 2013.


(A.K. Khurana)
Director (Pricing)