

No. 31015/12/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 25.01.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Eris Lifesciences Limited (hereinafter called the applicant) against notification S.O. No.02(E), dated 01/01/2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Rosuvastatin 20mg + Clopidogrel 75mg Capsules.

2. The applicant has contended as under:-

2.1 M/s Eris Lifesciences Ltd had applied for Price approval in form - I, separately for two different combinations of Rosuvastatin & Clopidogrel. NPPA vide S.O. No 02. Dated 01.01.2018 has notified retail price for both the combinations viz.

(i) Rosuvastatin 10 mg + Clopidogrel 75 mg — capsules Price of Rs.13.37 per capsule

(ii) Rosuvastatin 20 mg + Clopidogrel 75 mg — capsules Price of Rs.7.80 per capsule.

2. In this context, company stated that -

(a) Clopidogrel -75 mg Tablets is Scheduled formulation and hence, covered under Price Control as per DPCO 2013. The price of Clopidogrel 75 mg Tablets is notified as Rs. 6.57 + GST vide S.O. 1039 (E) dated 01.04.2017. As company is existing manufacturer of clopidogrel 75 mg tablets, the proposed combination including clopidogrel 75 mg is subject to price approval by NPPA in terms of DPCO 2013.

(b) Further the price of Rosuvastatin 20 mg Tablets, a non scheduled formulation, was fixed by NPPA under para 19 of DPCO at Rs. 23.17 per Tablet vide S.O. 1773 (E) dated 10.07.2014.

(c) As aforesaid, Company had applied for Price Approval in Form-I for Following Combinations:

(i) Rosuvastatin 10 mg + Clopidogrel 75 mg — capsules demanding Price of Rs. 16.00 per capsule.

(ii) Rosuvastatin 20 mg + Clopidogrel 75 mg — capsules demanding Price of Rs 20.00 per capsule.

(d) NPPA vide SO No 02(E) dated 01.01.2018 has issued price approval and fixed the following retail price for the said combinations:

(i) Rosuvastatin 10 mg + Clopidogrel 75 mg — capsules Price of Rs.13.37 per capsule.

(ii) Rosuvastatin 20 mg + Clopidogrel 75 mg — capsules Price of Rs.7.80 per capsule.

2.2 Company does not have any dispute in respect of the price notified for Rosuvastatin 10 mg + Clopidogrel 75 mg — capsules Price of Rs. 13.37 per capsule. Company stated that no working sheet has been provided or uploaded on the website of NPPA and hence, company is not aware about the considerations taken into account while calculating the Retail Price.

2.3 **In view of the aforesaid, company submitted that there is some error in calculation by NPPA. However company is unable to point the error in absence of working sheet.** Further, it is pertinent to note that the price of each formulation i.e. Rosuvastatin and Clopidogrel in single dosage form is much higher. Further the price notified on 01.01.2018 for the lower dose combination i.e. Rosuvastatin 10mg + Clopidogrel 75 mg is Rs. 13.37 per capsule whereas that of higher dose combination i.e. Rosuvastatin 20 mg + Clopidogrel 75 mg is Rs.7.80 per capsule. According to company the price of higher dose combinations should be around Rs. 16.50 per capsule. It appears that the price fixed for Rosuvastatin 20 mg + Clopidogrel 75 mg Capsules is not in conformity with para 5, 11 & 15 of DPCO-2013, if done so it would have to be on a much higher side.

2.4 In the light of above facts, Company requested this Department to Review the retail Price fixed by NPPA vide notification dated 01.01.2018 for Rosuvastatin 20 mg + Clopidogrel 75 mg capsules and to modify the retail price fixed for the aforesaid combination as the same is not in conformity to the provisions of DPCO, 2013.

3. **Comments of NPPA:**

3.1 The retail price of formulation fixed by NPPA, vide SO No 02 (E) dated 01.01.2018 as detailed below:-

Sl. No.	Name of the Formulation	Company's Product Composition	Notified Price(Rs)
1	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	7.80 per capsule

3.2 The Grievances of the company and NPPA's reply is as follow:

(i) **Company's Grievance:**

Company stated that they wanted to market various combinations of Rosuvastatin and Clopidogrel capsules, for which they had applied for price approval in form –I separately for two different combinations of Rosuvastatin and Clopidogrel.

NPPA vide S.O. No 02(E) dated 01.01.2018 has notified for both of the combination viz.:-

Rosuvastatin 10 mg + Clopidogrel 75 mg Rs 13.37 per capsule

Rosuvastatin 20 mg + Clopidogrel 75 mg Rs 7.80 per capsule

Company affirmed that they do not have any dispute in respect of price notified for Rosuvastatin 10 mg + Clopidogrel 75 mg at Rs 13.37 per capsule. It is pertinent to note that no working sheet has been uploaded on the website of NPPA and hence they are not aware about the considerations taken into account while calculating the retail price.

NPPA's Comments:

NPPA invited reference to 51st Authority meeting held on 15.12.2017 wherein it was decided that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. This decision has been endorsed at a high level meeting which has been communicated to all concerned. Accordingly, the price was fixed as per the above decision and therefore calculation sheet was not uploaded.

Company's Grievance:

Company reiterated that there was some error in calculation by NPPA. However they are unable to find out in absence of working sheet. Further it is pertinent to note that the price of each formulation i.e. Rosuvastatin and Clopidogrel in single dosage form is much higher. Further the price notified on 01.01.2018 for the lower dosage combination i.e. Rosuvastatin 10 mg + Clopidogrel 75 mg is Rs 13.37 per capsule whereas that of higher dosage combination Rosuvastatin 20 mg + Clopidogrel 75 mg is Rs 7.80 per capsule. According to them the price of higher dosage combination should be around Rs 16.50 per capsule. It appears that price fixed for Rosuvastatin 20 mg + Clopidogrel 75 mg is not in conformity with para 5, 11 and 15 of DPCO, 2013.

NPPA's Comments:

NPPA fixed the retail price of Rosuvastatin 20 mg + Clopidogrel 75 mg capsule manufactured by Synokem Pharmaceuticals Limited and marketed by M/s Eris Lifesciences Limited as Rs.7.80 per capsule vide S.O. 02(E) dated 01.01.2018 as per the decision taken in 51st Authority Meeting. However, on re-examination it is observed that this price for Rosuvastatin 20 mg + Clopidogrel 75 mg capsule was fixed inadvertently which was applicable for Rosuvastatin 20 mg + Aspirin 75 mg and NPPA has not fixed the retail price of Rosuvastatin 20 mg + Clopidogrel 75 mg earlier.

(ii) Company's Grievance:

Company therefore requested to modify the retail price fixed for Rosuvastatin 20 mg + Clopidogrel 75 mg as the same is not in conformity to the provision of DPCO, 2013.

NPPA's Comments:

Action in this regard will be taken on the basis of directive as per review orders.

4. Examination:

4.1 NPPA fixed the retail price of formulation **Rosuvastatin 20 mg + Clopidogrel 75 mg Capsules** vide SO 02(E), dated 01/01/2018 as Rs 7.80 per capsule. The retail price has been fixed on the basis of request made by M/s Eris Lifesciences Ltd. under para 2(u) of DPCO, 2013 and filed Form I for fixation of retail price for their formulation Rosuvastatin 20 mg + Clopidogrel 75 mg Capsules, being new drug.

4.2 NPPA stated that it was decided in 51st Authority meeting held on 15.12.2017 that wherever the application has been received by NPPA for any drug for which NPPA has already notified the price, the same would be extended to the subsequent applicants also. However, on re-examination it is observed that this price for Rosuvastatin 20 mg + Clopidogrel 75 mg capsule was fixed inadvertently which was applicable for Rosuvastatin 20 mg + Aspirin 75 mg and NPPA has not fixed the retail price of Rosuvastatin 20 mg + Clopidogrel 75 mg earlier.

4.3 It is worth mentioning here that the decision to extend the same retail price notified earlier for the same formulation is beyond the provisions of DPCO, 2013. However, **in the instant case, NPPA, itself admitted that the retail price of Rosuvastatin 20 mg + Clopidogrel 75 mg has not been fixed earlier and inadvertently extended the retail price fixed for Rosuvastatin 20 mg + Aspirin 75 mg. NPPA stated that action in this regard will be taken on the basis of directive as per review orders.**

4.4 In view of para 4.2 & 4.3 above, NPPA needs to be directed to **refix the retail price of new drug Rosuvastatin 20 mg + Clopidogrel 75 mg Capsules as per provision of para 5(1) read with para 9(4) of DPCO, 2013.**

5. Decision:

“NPPA is hereby directed to refix the retail price of new drug Rosuvastatin 20 mg + Clopidogrel 75 mg Capsules strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013, within a period of one month from the date of issue of the order.”

Issued on this date, the 8th day of June, 2018.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

Copy to:-

1. M/s Eris Lifesciences Limited, 8th Floor, Commerce House – IV, Prahlad Nagar, Ahmedabad-380015.
2. The Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, New Delhi-110001
3. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department’s Website