

**No. 31015/14/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on an application dated 27.01.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Zydus Healthcare 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 Company found that the price fixed by NPPA for a new drug formulation Rosuvastatin 20mg + Clopidogrel 75mg Capsules vide S.O. 02(E) dated 01.01.2018 at sr. no. 5 of the order is not in order as per DPCO, 2013. The details of the price fixed vide above referred order for Rosuvastatin 20mg + Clopidogrel 75mg Capsules is as below:

S.O. 02(E) dated 01/01/2018					
Sl. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
5	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd.	7.80

2.2 Calculation of ceiling price

Calculation of the Retail price of Rosuvastatin 20mg + Clopidogrel 75mg Capsules as per para 5(i) considering AWACS data is as below:

Rosuvastatin 20mg + Clopidogrel 75mg Capsules	
Sum of MAT value considered for price calculation (Rs. In Cr.)	6.30
Sum of PTR per unit considered for price calculation *	43.38
Number of Packs considered	3
Average PTR	14.46
Add: 16% Retailer Margin	2.31
Ceiling price (without local taxes)	16.77

***Details of Brand wise PTR and MAT (November'16)**

Sr. No.	Brand	Company	MAT (Rs. Cr.)	PTR per Capsule
1	ROSUF1T CV	AIANTA PHARMA LTD	3.3	15.39
2	NOVASTAT CV	LUPIN LTD	2.9	17.40
3	ROSYCAP CV	AKUMENT1S HEALTHCARE LTD	0.1	10.59

3.3 Anomaly in the price and strength

There is anomaly in the prices of combination formulations of Rosuvastatin + Clopidogrel in capsules as notified by NPPA.

Sr. no.	Product	S.O. No. and date	Notified Retail Price
1	Rosuvastatin 5 mg + Clopidogrel 75mg Capsules	4131(E) 22.12.2016	10.35
2a.	Rosuvastatin 10mg + Clopidogrel 75mg Capsules	4131(E) 22.12.2016	13.94
2b.	Rosuvastatin 10mg + Clopidogrel 75mg Capsules	3915(E) 18.12.2017	13.37
3	Rosuvastatin 20mg + Clopidogrel 75mg Capsules	3915(E) 18.12.2017	7.80

It is observed from above table that the price of higher strength i.e. Rosuvastatin 20mg is lower as compare to lower strength i.e. Rosuvastatin 10mg or Rosuvastatin 5mg (Strength of Clopidogrel is same in all formulations).

Details of notification issued by NPPA is as below.

S.O. 4131(E) dated 22.12.2016				
Sl. No.	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
18	Each hard gelatin capsule contains: Rosuvastatin calcium eq. to Rosuvastatin 5mg (as pellets) Clopidogrel Bisulphate eq. to Clopidogrel 75mg (as pellets)	1 Capsule	M/s Synkem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	10.35
19	Each hard gelatin capsule contains: Rosuvastatin calcium eq. to Rosuvastatin 10mg (as pellets) Clopidogrel Bisulphate eq. to Clopidogrel 75mg (as pellets)	1 Capsule	M/s Synkem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	13.94

S.O. 3915(E) dated 18.12.2017					
2	Rosuvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium	1 Capsule	M/s Aeon Formulation Pvt. Ltd. / M/s USV	13.37

	[Roseday CV10]	IP eq. to Rosuvastatin (As granules] 10mg, Clopidogrel Bisulphate IP eq. to Clopidogrel (As a film coated tablet] 75mg		Private Limited	
15	Rosuvastatin + Clopidogrel Capsule (Roistar CV 10/75]	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)	1 Capsule	M/s Synkem Pharmaceuticals Ltd./ M/s Unichem Laboratories Ltd.	13.37
26	Rosuvastatin + Clopidogrel Capsule	Each Hard gelatin capsule contains: Rosuvastatin 10mg, Clopidogrel 75mg	1 Capsule	M/s Synkem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	13.37

2.4 Submission:

- (i) NPPA may please be directed to recalculate the Retail Price of Rosuvastatin 20mg + Clopidogrel 75mg Capsules in accordance with details given above as per para 5(i) of DPCO 2013.
- (ii) The price of higher strength should not be lower as compared to price of lower strength and therefore price notification needs to be revised with retrospective effect [i.e. from date of notification].
- (iii) Company requested this Department to correct the Retail Price as per DPCO, 2013.

3. Comments of NPPA:

3.1 The retail price of formulation fixed by NPPA, vide S.O. No. 02(E) dated 01/01/2018 is detailed below:-

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

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

(i) Company's Grievance:

Company found that the price fixed by NPPA for a New Drug formulation Rosuvastatin 20 mg +Clopidogrel 75 mg capsule vide S.O. 02(E) dated 01.01.2018 is not in order as per DPCO, 2013, and submitted PTR and MAT value of various brands available in the market.

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 Zydus Healthcare Limited as Rs. 7.80 per capsule vide S.O. 02(E) dated 01.01.2018 as per the decision taken in 51th Authority Meeting. However, on re-examination it is observed that this price for Rosuvastatin 20 mg + Clopidogrel 75 mg capsule was fixed, which was applicable for Rosuvastatin 20 mg + Aspirin 75 mg and retail price of Rosuvastatin 20 mg + Clopidogrel 75 mg capsule was not fixed by NPPA earlier.

(ii) Company's Grievance:

Company claimed ceiling price Rs. 16.77 for this formulation raised on AWACS data. Company also stated that NPPA notified retail price Rs. 10.35 and 13.94 for a formulation having Rosuvastatin 5 mg/10 mg + Clopidogrel 75 mg per capsule vide S.O. No. 4131 (E) dated 22.12.2016. Company also pointed out that NPPA notified retail price Rs. 13.37 and Rs. 7.80 for a formulation having Rosuvastatin 10 mg + Clopidogrel 20 mg capsule vide S.O. No. 3915 (E) dated 18.12.2017.

NPPA's Comments:

It is a factual statement, hence no comments.

(iii) Company's Grievance:

Company requested to correct the retail price as per 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.

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. 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. 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 5.2 & 5.3 above, NPPA needs to be 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 by considering the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the new drug price as per the simple average formula as contained in para 4(1) of DPCO, 2013.

5. Government Decision:

“NPPA is hereby directed to refix the retail price of new drug Rosuvastatin 20 mg + Clopidogrel 75 mg 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 29th day of May, 2018.

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

Copy to:-

1. M/s Zydus Healthcare Limited, Bhaghey Khola, N.H. No.10, Majhitar, Rangpo, East Sikkim-737 136.
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