

No. 31015/88/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A wing, Shastri Bhawan
New Delhi 110 001

ORDER BY REVIEWING AUTHORITY UNDER PARA 31 OF DPCO,2013

Subject: Review application of M/s Cadila Healthcare Limited against S.O. No. 2965(E) dated 15/09/2016 for Price fixation of formulation of Rosuvastatin + Aspirin Capsule (Zyrova ASP 150) issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: (1) Review application dated 30/09/2016
(2) NPPA notification under review S.O No. 2965(E) dated 15/09/2016

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cadila Healthcare Limited(hereinafter called the petitioner) against notification S.O.2965(E) dated 15/09/2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Rosuvastatin + Aspirin Capsule (Zyrova ASP 150).

2. **The petitioner has submitted as under:**

(ii) The Retail Price fixed by NPPA for Rosuvastatin + Aspirin Capsule (Zyrova ASP 150) vide notification No. S.O. 2965(E) dated 15th September, 2016 at Serial No. 8 of the notification **is not correct**. The details of the price fixed vide above referred notification is as below:

<u>Sl. No.</u>	<u>Name of the Scheduled Formulation /Brand Name</u>	<u>Strength</u>	<u>Unit</u>	<u>Manufacturer & Marketing Company respectively</u>	<u>Retail Price (Rs)</u>
1	2	3	4	5	6
8	Rosuvastatin + Aspirin Capsule (Zyrova ASP 150)	Each hard gelatin capsule contains: Rosuvastatin Calcium eq. to Rosuvastatin-10mg (as film coated tablets) Aspirin-150mg (as entric coated pellets)	10 Capsules	M/s Windlas Biotech Ltd & M/s Cadila Healthcare Ltd.	50.05 (10 Capsules)

(ii) The draft version of Proposed Price Calculation Sheets for 26 Medicines was placed on website of NPPA on 12.08.2016. **The summary of the computation of Retail Price based on Dec-2015 data under Para 4 of DPCO 2013 as given in the working sheet is as below:**

Sum of MAT value considered for price calculation (Rs. In Lakhs)	247.50
Sum of PTR per unit considered for price calculation	26.20
Number of Packs considered	5
Average PTR	5.24
Add : 16% Retailer Margin	0.84
Retail Price (without local taxes)	Rs.6.08/capsule

Thus, the Retail Price notified for Rosuvastatin + Aspirin Capsule (Zyrova ASP 150) vide S.O. 2965(E) dated 15th September, 2016 at Serial No. 8 of the notification is not as per the Draft Sheet of the Proposed Price Calculation as placed on website of NPPA on 12.08.2016.

(iii) Further the company also referred to this Department's Review Order dated 30.08.2016 in the matter of M/s. FDC Limited (Order No. 31015/27/2015-PI.I) where in the following decision of the Government has been communicated to the NPPA:

“Review application of the company is accepted and NPPA is directed to fix the price as per the provisions of DPCO 2013 rather than deciding the ceiling prices on its own principles which are not as per the provisions of DPCO, 2013.”

The above order was based on the examination that DPCO 2013 has provision of Para 5(1) and Para 9(4) whereby NPPA is required to consider the PTR of available drugs in the market, take simple average of all those which have more than 1% market share and consider the price as per the simple average formula contained in Para 4(1) of DPCO 2013. **The decision of the Authority to apply any other formula amounts to amending the provisions of DPCO 2013 for which NPPA has no authority.**

(iv) In case of ZYROVA ASP 150 NPPA has once again deviated from the laid down provision of Para 4(1) of DPCO 2013 and has not stuck to the simple average pricing formula. The Draft Sheet placed on the website on 12.08.2016 was in compliance of the simple average formula.

In view of the above facts, the company requested this Department to give consideration to their submission and direct the NPPA to notify the retail price of ZYROVA ASP CAPSULE as Rs. 6.08 per capsule.

(v) Through this submission, the company also undertake the implementation of the Notified Price of ZYROVA ASP 150 CAPSULE. To this effect the company enclosed copy of Form V.

3. **Comments of NPPA**

(i) NPPA has fixed the retail price of Rs. 50.05 per 10's capsules based on retail price fixed for Rosuvastatin 10mg & Aspirin 150mg capsule of M/s GKM New Pharma (manufacturer) and M/s Intas Pharma Ltd (marketing company) as per the decision of 19th Authority meeting held on 10.12.2014. This is as per the existing practice of 14th Authority meeting held on 23.4.2014. The Authority decided that in case of Form-I applications, price fixed by NPPA shall be valid for one year for formulations having same composition and strength and no increase in the price will be allowed. However, in case the current price worked out / claimed is lower than the existing notified price, the benefit of lower price has to be passed on to the consumers. The Authority took a conscious decision in consumer interest at large in confirmation to various pronouncements and observations of Hon'ble Supreme Court in several cases.

(ii) The Authority's decision is based on the rationale of uniformity of price being in competition, thus ensuring better availability of medicines as per NPPA's mandate under para 21 of DPCO, 2013. Further, NPPA's order is in conformity with the overall scheme of things under DPCO, 2013 and not prohibited under the law.

4. **Examination:**

The petitioner company has filed review petition against price fixation of formulation Rosuvastatin + Aspirin Capsule (Zyrova ASP 150) vide SO 2965(E), dated 15th September, 2016. It is a new drug under NLEM 2015. In this case, the NPPA has fixed the price of aforesaid formulation based on the decision of their 19th Authority Meeting held on 10.12.2014, wherein the NPPA's Authority decided that in case of Form-I applications, price fixed by NPPA shall be valid for one year for formulations having same composition and strength and no increase in price will be allowed. Provision of para 5(1) read with para 9(4) of DPCO 2013 provides to consider 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 contained in para 4(1) of DPCO 2013. The decision of the NPPA's Authority Meeting to apply any other formula amounts to amending the provisions of DPCO 2013, for which NPPA has no authority.

5. **Decision of the Government:**

After examination of the case, the Government has decided as under:

“NPPA is hereby directed to fix the price as per the provisions of para 5(1) read with para 9(4) of DPCO 2013 and consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the fixation of drug price as per the simple average formula contained in para 4(1) of DPCO 2013.”

Issued on this date, the 18th day of September, 2017.

(Jai Priye Prakash)
Secretary
For and on behalf of the President of India

To

1. M/s. Cadila Health Care Ltd.
Zydus Tower
Satellite Cross Roads
Ahmedabad – 380 015.
2. Member Secretary
National Pharmaceutical Pricing Authority
YMCA Cultural Centre Building
New Delhi – 110 001.

Copy to:

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D. NIC for uploading the order on Department's website.